(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
10 September 2004 (10.09.2004)

PCT

(10) International Publication Number
WO 2004/075741 A2

(51) International Patent Classification[7]: A61B 1/32

(21) International Application Number: PCT/US2004/005487

(22) International Filing Date: 25 February 2004 (25.02.2004)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/449,857 25 February 2003 (25.02.2003) US

(71) Applicant *(for all designated States except US)*: APPLIED MEDICAL RESOURCES CORPORATION. [US/US]; 22872 Avenida Empresa, Rancho Santa Margarita, CA 92688 (US).

(71) Applicant and
(72) Inventor *(for all designated States except US)*: PINGLETON, Edward, D. [US/US]; 26993 Albillo Court, Laguna Niguel, CA 92677 (US).

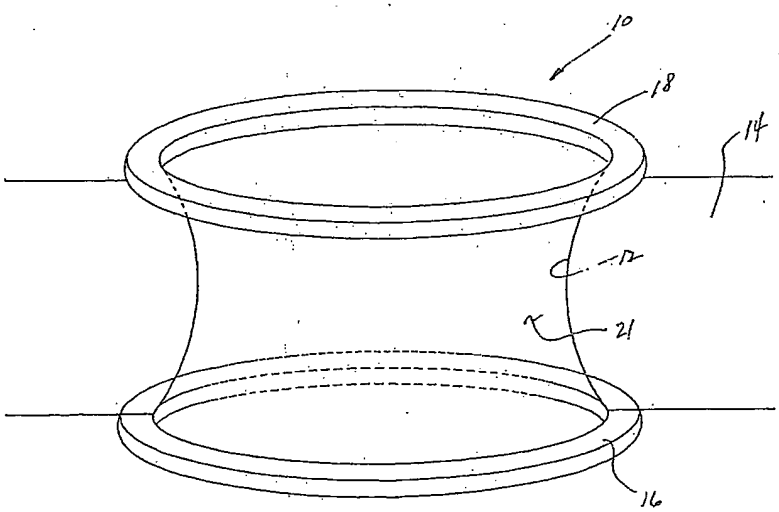
(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: BRUSTAD, John [US/US]; 34056 Formosa Drive, Dana Point, CA 92629 (US). EWERS, Richard [US/US]; 1437 W. Malvern, Fullerton, CA 92833 (US). HILAL, Nabil [US/US]; 25291 Spindlewood, Laguna Niguel, CA 92677 (US). ADLPARVAR, Payam [US/US]; 21861 Michigan Lane, Lake Forest, CA 92630 (US). TAYLOR, Scott, V. [US/US]; 27851 Encanto, Mission Viejo, CA 92692 (US). DULAK, Gary, R. [US/US]; 6 Mojo Court, Newport Beach, CA 92663 (US). DUNN, Michael, J. [US/US]; 2408 N. Louise, Santa Ana, CA 92706 (US). MORALES, Norman, L. [US/US]; 38700 Tyson Lane, #307, Fremont, CA 94536 (US). HART, Charles, C. [US/US]; 126 Marvin Gardens, Summerville, SC (US). BOWES, Robert, R., II [US/US]; 28520 Wood Canyon, #81#2212, Aliso Viejo, CA 92656 (US).

(74) Agent: MYERS, Richard; 22872 Avenida Empresa, Rancho Santa Margarita, CA 92688 (US).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD,

[Continued on next page]

(54) Title: WOUND RETRACTOR FOR USE IN HAND ASSISTED LAPAROSCOPIC SURGERY



(57) Abstract: A surgical retractor (10) is adapted for use in opening an incision (12) in a body wall (14) to facilitate access into a body cavity. The retractor includes an interior anchor (16) that is disposed interiorly of the body wall and an exterior tensioning device (56) that is disposed exteriorly of the body wall. At least one tension element (21) is coupled to the interior anchor and adapted to pass through the incision to engage the exterior tensioning device. Engaging elements (59, 62) are provided on the exterior tensioning device to engage the tension element and to maintain a tensile force on the tension element as it passes through the incision. Multiple concentric rings can also be used to maintain a tensile force on the tension element.

WO 2004/075741 A2

MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— *without international search report and to be republished upon receipt of that report*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

WOUND RETRACTOR FOR USE IN HAND ASSISTED LAPAROSCOPIC SURGERY

Cross Reference to Related Applications

This is a non-provisional application which claims the benefit of provisional application Serial No. 60/449,857 filed on February 25, 2003, and entitled Hand-Assisted Laparoscopy Apparatus And Method, which is fully incorporated herein by reference.

BACKGROUND OF THE INVENTION

Field of the Invention

This invention relates generally to devices and methods associated with laparoscopic surgery, and more specifically, to wound retractors used in hand-assisted laparoscopic surgeries.

Discussion of Related Art

During laparoscopic surgery, it is desirable to inflate the abdominal cavity in order to increase the volume of the working space. This is accomplished with an insufflation gas which must be maintained at a pressure sufficient to elevate the abdominal wall. Maintaining the pressure of the insufflation gas is difficult when it is also desirable to insert instrumentation or even the surgeon's hand through the abdominal wall.

Currently, several devices exist that accomplish this surgical need although they suffer from drawbacks such as difficult placement and cumbersome use. A wound retracting device that allows the surgeon to easily locate the device and provide a solid base for an instrument or hand seal would be of particular advantage.

Wound retraction offers the following advantages. Initially it removes the tissue pressure from the surgeon's wrist during hand-assisted laparoscopic surgery. Additionally, it can offer protection for the tissue at the wound site from abrasion or bacteria or other contaminants. Furthermore, it allows organs to be removed, such as donor kidneys, while minimizing the risk of damage to the organ. It also allows surgery to be performed through the retracted wound site even when the sealing device has been removed. Thus, it is desirable that the wound be retracted, protected and fixed while maintaining an insufflation seal.

SUMMARY OF THE INVENTION

In accordance with the present invention, a wound retractor is adapted for use in laparoscopic surgery and particularly hand-assisted laparoscopic surgery. An anchor is disposed interiorly of a wound site or incision and an exterior tensioning device is disposed exteriorly of the incision site. At least one tension element is disposed to extend through the incision between the anchor and the tensioning device. This tension element may comprise a tubular sheath, for example, which is positioned with its axis extending through the incision. Operation of the tensioning device tends to

stretch the sheath axially, thereby creating a radial force on the incision. This force tends to enlarge the incision thereby relieving pressure on the surgeon's wrist during hand-assisted laparoscopic surgery. Many types of tension elements as well as tensioning devices are contemplated.

In one aspect, the invention includes a surgical retractor adapted for use in opening an incision in a body wall to facilitate access into a body cavity. An interior anchor is adapted for disposition interiorly of the body wall while an exterior tensioning device is adapted for disposition exteriorly of the body wall. At least one tension element is connected to the interior anchor and adapted to pass through the incision to engage the exterior tensioning device. The tensioning device engages the tension element at a predetermined location along the tension element to maintain a tension force on the tension element as it passes through the incision.

In another aspect, the surgical retractor includes a tubular sleeve having an axis extending between a proximal end and a distal end. A distal ring is disposed at the distal end of the sleeve while a proximal ring is disposed at the proximal end of the sleeve. A middle ring is axially movable on the sleeve between the proximal ring and the distal ring. The distal ring is adapted to retain the distal end of the sleeve interiorly of the body wall while the proximal ring is adapted to retain the proximal end of the sleeve exteriorly of the body wall. The middle ring and the proximal ring have properties for cooperating to tension the sleeve between the middle ring and the distal ring to retract the incision.

In a further aspect, the invention includes the tubular sleeve, the distal ring and at least one proximal ring disposed along the sleeve at a predetermined location relative to the distal ring. Circular means is provided for engaging the proximal ring at the predetermined location and around the incision to tension the sleeve through the incision and between the distal ring and the at least one proximal ring.

An associated method for retracting an incision extending through a body wall of a patient, includes the steps of providing a tubular sleeve having an axis extending between a proximal end and a distal end. The distal end of the sleeve is introduced through the incision to the distal side of the body wall leaving the proximal end of the sleeve on the proximal side of the body wall. The distal end of the sleeve is then anchored on the distal side of the body wall and the sleeve is axially tensioned to retract the incision. Fixing the proximal end of the sleeve to the proximal side of the body wall maintains tension on the sleeve with a concomitant retraction of the incision.

These and other features and advantages of the invention will become more apparent with a description of preferred embodiments and reference to the associated drawings.

DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of one embodiment of a surgical retractor in accordance with the present invention;

FIG. 2a is a side perspective view in axial cross section illustrating the surgical retractor of FIG. 1 operative disposed on the body wall;

FIG. 2b is an end elevation view showing one end of the retractor of FIG. 2a and illustrating a radial force acting on the incision;

FIG. 2c is an end elevation view similar to Fig 2b and illustrating both axial and radial forces acting on the incision;

FIG. 3 is a perspective view similar to FIG. 1 and illustrating tension members in the form of elastomeric bands;

FIG. 4 is a perspective view similar to FIG. 3 and illustrating tension members embedded in an elastomeric sheath;

FIG. 5 illustrates a side elevation view of the body wall and incision illustrating a further embodiment of the retraction member wherein a proximal ring is operable with a sleeve clamp;

FIG. 6 is a perspective view of an additional embodiment wherein the tension members comprise ladder straps;

FIG. 7a is a perspective view of an embodiment including tension members in the form of zip ties;

FIG. 7b is an enlarged view of a lock structure for holding an associated zip tie at a preferred location;

FIG. 8 is a perspective view of an embodiment wherein the tension members are formed as knotted ropes;

FIG. 9 is a side elevation view of a body wall in combination with a surgical retractor having a threaded proximal ring engagable by a threaded sealing cap;

FIG. 10 is a perspective view in axial cross section of a further embodiment of the retractor including a middle ring;

FIG. 11a is a side elevation view illustrating placement of the distal or peritoneal ring with the tubular sheath extending through the incision;

FIG. 11b is a side elevation view illustrating the application of tension to the tubular sheath resulting in retraction of the incision;

FIG. 12 is a side perspective view in axial cross section illustrating an initial step in the operation of the three-ring embodiment of FIG. 10;

FIG. 13 is a side perspective view in axial cross section illustrating an additional step in the operation of the three-ring embodiment;

FIG. 14 is a side perspective view in axial cross section illustrating a further embodiment wherein the middle ring is retained at a preferred location along the sheath by an external clip;

FIG. 15 is a side perspective view in axial cross section illustrating a plurality of hoops each disposed at an associated axial position and adapted to receive a moveable ring;

FIG. 16 is a side perspective view in axial cross section illustrating a plurality of tracks each disposed at an associated axial position along the sheath and adapted to receive an external ring with a mating groove.

FIG. 17 is a side perspective view in axial cross section illustrating a further embodiment including a middle ring and a complimentary clamping ring;

FIG. 18 is a side perspective view in axial cross section illustrating a plurality of middle rings, each fixed to the sheath at an associated location and operable in accordance with the method steps illustrated in Figures 19 and 21.

FIG. 19 is an end view showing operation of the interlocking rings in the embodiment of FIG. 18, and illustrating the sheath being pulled up from the incision;

FIG. 20 is an end view similar to FIG. 19 and illustrating retention of the sheath by a wedge element;

FIG. 21is an end view similar to FIG. 20 and illustrating a separation of the inner locking rings to free the tubular sheath;

FIG. 22 is an end view similar to FIG. 20 and illustrating a further embodiment including a unidirectional roller;

FIG. 23 is a side perspective view in axial cross section and illustrating an embodiment with interlocking rings in the form of wedges;

FIG. 24 is an end view similar to FIG. 23 and illustrating a further embodiment wherein the sheath includes a plurality of bumps operable with a ratchet disposed on the associated rings;

FIG. 25 is an axial cross section view of a further embodiment including an expandable foam, the foam being shown in a compressed state.

FIG. 26 is an axial cross section view similar to FIG. 25 and illustrating the expandable foam in an expanded state;

FIG. 27 is an axial cross section view of an embodiment including a sealing ring with a groove sized to receive an external O-ring associated with the tubular sheath, the O-ring being illustrated in an initial spaced relationship with the sealing ring;

FIG. 28 is an axial cross section view similar to FIG. 27 with the O-ring illustrated in an interlocking relationship with the groove of the sealing ring;

FIG. 29 is an axial cross section view illustrating a further embodiment wherein the middle ring is fixed to the sheath, the embodiment shown being in one of four axial-length positions wherein the middle ring is disposed within the incision;

FIG. 30 is an axial cross section view similar to FIG. 29 and illustrating a second axial length achievable with the three-ring embodiment;

FIG. 31 is an axial cross section view illustrating a third axial length achievable with the three-ring embodiment;

FIG. 32 is an axial cross section view illustrating a first step toward achieving a fourth axial length of the three-ring embodiment;

FIG. 33 is a side elevation view illustrating a second step toward achieving the fourth length of the three-ring embodiment.

PREFERRED EMBODIMENTS AND BEST MODE OF THE INVENTION

A wound retractor is illustrated in Figure 1 and designated by the reference numeral 10. The retractor 10 is adapted for use with respect to a wound site or incision 12. By way of example, the incision 12 may be formed in a body wall, such as the abdominal wall 14. Through such a wall 14, the incision 12 will typically provide access for surgical instruments and even the surgeon's hand in the case of hand-assisted laparoscopy.

The basic concept of retracting and protecting the wound site or incision 12 is illustrated in the perspective view of Figure 1. In this embodiment, the retractor 10 includes two O-rings 16 and 18 that are connected along an axis 21 by an elastic sheet or sheath 21. The lower O-ring 16 is placed into the peritoneum and the upper O-ring 18 is stretched away from the lower O-ring 16. Once the elastic sheath 21 has been stretched to a distance greater than the thickness of the abdominal wall, the upper O-ring 18 is placed on the surface of the skin. Since the diameters of the O-rings are larger than that of the incision 12, they will have sufficient footing to maintain the tension between two rings 16 and 18. This tension is created by the elastic material that has been stretched and held at a distance greater than its axial length in the natural state.

Figure 2a shows a simple schematic of the O-ring dynamics illustrated in Figure 1. The elastic sheath 21 acts as a circumferential spring 23 around the incision 12, that evenly distributes the tension between the two O-rings. In addition, the elastic

sheath 21 will provide a circumferential retraction of the wound site or incision 12 to facilitate the passage of instruments and/or the surgeon's hand. This circumferential retraction of the incision 12 is illustrated in Figure 2b by the arrow 25.

The amount of tension force between the two O-rings 16, 18 can be controlled by the elasticity of the elastic sheath. If the desire is to accommodate a larger range of abdominal wall thicknesses, then a sheath material with a higher elasticity will be chosen to allow for greater stretch.

Figure 3 illustrates the "sandwiching" of the abdominal wall 14 between the two O-rings 16, 18 by using elastic tension members 27, such as rubber bands 30. The use of elastic tension members 27 allows for a greater range of wall thicknesses because the tensions can be selected at the time of application. For instance, the user would make the incision 12 and measure the actual thickness of the abdominal wall 14. He would then choose the appropriate tension members 27. This gives the user a high degree of versatility with the retractor 10.

Figure 4 illustrates a different embodiment which also provides increased versatility. This design is not limited by the fixed distance between the O-rings of the assembly. Rather, the lower O-ring 16 will have the elastic sheath 21 attached and the upper O-ring 18 will comprise a separate assembly 32. Initially, the lower O-ring 16 is placed into the peritoneal cavity. Then the elastic sheath 21 is pulled taut and secured onto a plurality of hooks 34 located around the abdominal O-ring 18. This allows the user to fix the O-rings 16, 18 to the abdominal wall 14 regardless of its thickness.

Figure 5 shows an additional variation wherein the elastic sheath 21 is attached to the abdominal ring 18 using a clamping method. In this case, the abdominal ring 18 is bifurcated and includes an abdominal portion 36 and a clamping portion 38. The sheath 21 is drawn from the distal ring 16 upwardly through the incision 12 and between these portions 36 and 38 of the ring 18. When the sheath 21 is drawn taught, and the clamping portion 38 of the ring 18 is seated on the abdominal portion 36, the tension on the sheath 21 can be maintained. This construction will work well with either elastic or non-elastic sheath materials.

Figure 6 illustrates another variation wherein the elastic material 21 is attached to the abdominal ring using "ladder straps" 14 that are connected to the external surface of the elastic sheath 21. Once the preferred tension of the elastic sheath 21 has been attained, the user simply hooks the appropriate "rung" 43 onto an associated hook 45 located on the abdominal ring 18. Once again this construction will function well with either an elastic or non-elastic sheath material.

Figure 7A shows a structure which sandwiches the abdominal wall 14 between the two O-rings 16, 18 using "zip ties" 47. After the lower O-ring 16 has been placed, the "zip ties" 47 are pulled tight to fix the O-rings 16, 18 to the abdominal wall 14. As illustrated in Figure 7B, each zip tie 47 can be drawn through a hole 50 in the external ring 18 and locked in place at a predetermined location by a lever 52. Movement of the zip tie 47 through the hole 50 can be rendered unidirectional by appropriate placement of the lever 52.

Figure 8 shows a method of sandwiching the abdominal wall 14 between the two O-rings 16, 18 using "knotted ropes" 54. After the lower O-ring 16 has been placed, the knotted ropes 54 can be tensioned and secured into notches or holders 56 located on the abdominal ring 18.

An additional embodiment of the wound retractor 10 is illustrated in Figure 9. This embodiment is adapted for opening the incision 12 and for maintaining the incision 12 in the open configuration to allow access across the abdominal wall 14. The device includes the sheath 21 which extends between the distal O-ring 16, and a proximal ring 56 which is provided with external threads 58. An outer ring 59 is provided with a distal sealing ring 60 and internal threads 61 which mate with the threads 58 of the ring 56. The outer ring 59 is adapted to receive a sealing cap 62. With the external threads 58 of the ring 56 mated with the internal threads 61, the sealing cap 62 can be turned to rotate the outer ring 59. As the outer ring 59 turns, the inner ring 56 is drawn upwardly from the abdominal wall 14 to stretch the sheath 21. An opposing force is directed downwardly on the ring 59 pressing the sealing ring 60 into sealing engagement with the outer surface of the abdominal wall 14. As in previous embodiments, the peritoneal O-ring 16 attached to the distal end of the sheath 21 is designed to be placed inside the incision 12 while the ring 18 remains external to the incision 12.

Once the peritoneal O-ring 16 is placed inside the incision 12, the outer ring 56 is rotated clockwise relative to the ring 56. This opens the incision 12 and draws

both the sealing ring 60 and the peritoneal O-ring 16 into the abdominal wall 14. A primary seal is created between the peritoneal O-ring 16 and the abdominal wall 14, while a secondary seal is formed between the base of the outer ring 59 and the exterior abdominal wall 14. The sealing cap 62 can then be attached to the proximal end of the outer ring 59 to permit insufflation and facilitate a laparoscopic procedure, such as a gastric bypass, to be performed. The sealing cap 61 can be removed at any time to allow transition from laparoscopic surgery to open surgery.

Another embodiment of a wound retractor 10 is illustrated in Figure 10 wherein the device includes the thin film sheath 21 which lines the incision 12 to prevent or limit the risk of portsite metastasis. The rings 16, 18 are attached to opposing ends of the sheath 21 while a third ring 65 is movable generally in the middle of the sheath 21. After inserting the peritoneal ring 16 inside the incision 12, retraction is achieved by pulling the sheath 21 upwardly from the incision 12. Retraction is maintained by preventing the sheath 21 from pulling back into the incision 12. Figure 11a illustrates the initial placement of the peritoneal or distal ring 16 with the sheath 21 extending through the incision 12. The ultimate tensioning of the sheath, for example, along arrows 67, and the resulting retraction of incision 12 is illustrated in Figure 11b.

With this device, retraction is achieved by positioning the proximal ring 18 above the movable ring 65, and pulling the sheath upward from the incision 12. The sheath 21 is prevented from pulling back into the incision 12 by stretching the movable ring 18 out, around, and under the movable ring 65, as illustrated in Figure 12.

The degree of retraction is dependent on the amount of tension on the sheath 21 as it is pulled upwardly from the incision 12, which in turn is dependent on the height of the movable ring 65 above the abdominal wall 14. This height can be adjusted by moving the ring 65 along the sheath 21, then locking the ring 65 in place with the outer ring 18.

Clips 68 may be used to lock the movable ring 65 at the appropriate height as illustrated in the embodiment of Figure 14. Alternatively a series of open loops 69 (Figure 15) or tracks 70 (Figure 16) can be located at different distances along the sheath 21 to hold the movable ring 65 at different heights. In the embodiment of Figure 15, a movable ring 72 can be provided for insertion into one of the loops at the desired height above the distal ring 16. In the embodiment of Figure 16, a ring 152 can be provided with a cross section complimentary to that of the tracks 70 so that the ring 152 is maintained at a predetermined distance above the distal ring 16.

One advantage of the three-ring embodiments is that they enable the surgeon to retract and protectively cover the incision 12 while easily adjusting the device to accommodate variations in abdominal wall thickness. The device provides an airtight seal around the incision 12 thus allowing an airtight cap or access port to be attached to enable laparoscopic surgery. Retraction is achieved relatively quickly with only one or two motions required to pull the sheath 21 up from the incision 12.

In a slight variation on the three-ring embodiments, it will be apparent that a plurality of rings 74, 76, 78 & 81 can be attached to the sheath 21 between the

distal ring 16 and the proximal ring 18 as shown in Figure 17. In such an embodiment, any one of the plurality of rings 74-81 can be selected for its predetermined distance from the distal ring 16. In this case, the selected ring (such as the ring 76) and all rings between the selected ring and the exterior proximal ring 18 (such as the rings 78 and 81) can then be rolled into a bundle, as previously discussed with reference to Figures 12 and 13.

Figure 18 shows an embodiment similar to that of Figure 10, but including a set of interlocking rings 83 which are slideable along the sheath 21. These rings 83 include a base ring 85, a middle ring 87 and a top ring 90, best shown in Figure 19.

After inserting the peritoneal ring 16 inside the incision 12, the interlocking rings 85-90 can be pushed down to rest on the abdomen. Retraction is achieved by pulling the sheath 21 upward from the incision 12 and through the interlocking rings 83, which are kept pressed against the abdominal wall 14.

Retraction is maintained by preventing the sheath 21 from pulling back into the incision 12 by means of a one-way mechanism 92 within the interlocking rings 83. The sheath 21 slides easily through the interlocking rings 83 in one direction upwardly of the incision 12 as illustrated in Figure 19. However, any attempts to draw the sheath 21 backwardly through the interlocking rings 83 is resisted by the one-way mechanism 92, which in this case is carried by the top ring 90 and which becomes wedged in this case between the base ring 85 and the middle ring 87, as shown in

Figure 20. Disengaging or separating the interlocking rings 83 will allow the sheath 21 to move in the opposite direction into the incision 12, as illustrated in Figure 21.

The one-way mechanism 92 can also be composed of a one-way roller 94 which engages the sheath 21 and permits movement in only one direction, as shown in Figure 22. Alternately, a pair of wedge rings 96 and 98 can be used as shown in Figure 23. The rings 96, 98 can be pressed together manually or clamped onto the sheath 21 automatically as the sheath 21 tends to pull down into the incision 12. These rings 96, 98 can then be released by pulling the sheath 21 up from the incision 12, as shown in Figure 23. Bumps, over-braid, treads or coatings on the sheath 21 can be added for additional traction with the one-way mechanism in the above examples. Alternatively, features such as indentations or protrusions 101 can be provided on the sheath 21 to cooperate with a ratchet mechanism 103 to facilitate unidirectional movement of the sheath 21 through the interlocking rings 83, as illustrated in Figure 24.

One advantage of the interlocking rings 83 is that they enable the surgeon to retract and protectively cover the incision while permitting adjustment of the retractor 10 to variations in abdominal wall thickness. The device provides an airtight seal around the incision 12, thus allowing an airtight cap or access port to be attached to facilitate laparoscopic surgery. Furthermore, usage is simpler than for other devices that require the sheath to be folded, hooked or secured with additional steps. Furthermore, with these embodiments, retraction can be achieved with one motion by grasping the proximal ring 18 pulling it up from the incision 12 and then releasing it.

A further embodiment of the wound retractor 10, illustrated in Figures 25 and 26, includes an expandable foam ring 105. This device includes a base 107 with an air tight pocket 109 configured to receive the foam ring 105. Communicating with the pocket 109 is a manually actuated valve 110 which permits the ingress of air to inflate the foam ring 105. The foam ring 105 is initially compressed and the valve 110 closed to effect a low profile state.

Once the peritoneal O-ring 16 has been placed inside the incision 12, the valve 110 can be opened and the foam ring 105 expanded as air enters the pocket 109. The foam 105 is allowed to expand to a high profile state illustrated in Figure 26, which retracts the incision 12 to an open state. A sealing cap 112 can then be attached to the ring 18 and the patient can be insufflated with carbon dioxide to facilitate a laparoscopic procedure The sealing cap 112 can be removed at any time to allow transition from laparoscopic surgery to open surgery.

To remove the wound retractor 10 from the patient, the surgeon simply opens the valve 110 and pulls the peritoneal O-ring 16 out through the incision 12. While an expandable foam ring 105 is described, additional materials could be utilized which expand upon contact with the inlet air.

A further embodiment of the wound retractor is illustrated in Figure 27 and 28. This embodiment includes the sheath 21 which lines the incision 12 to prevent or limit the risk of portsite metastasis. The device includes a base 118 with a sealing ring 121, which is adapted to seal against the abdominal 14 of the patient. The external

O-ring 18 is adapted to be rolled, as shown by arrows 123, in order to gather the thin film sheath 21. As the sheath 21 is axially shortened, the sealing ring 121 of the base 118 is pressed against the exterior abdominal wall 14. In order to maintain this sheath tension and base seal, the external O-ring 18 is configured to lock into an annular groove 125 in the base 118. This final configuration, illustrated in Figure 28, can be covered with the sealing cap 61.

In this embodiment, the peritoneal O-ring 16 is designed to be placed inside the incision 12 while the external O-ring 18 remains external to the incision 12. The base 118 is configured to move freely between the O-rings 16, 18. Once the peritoneal O-ring 16 is placed inside the incision 12 and into the peritoneal cavity, the external O-ring 18 is continuously rolled or inverted, retracting the incision to an open state and also drawing both the external O-ring 18 and the peritoneal O-ring 16 towards the abdominal wall 14. Once all of the slack in the sheath 21 has been taken up, the external O-ring 18 can be pushed into the groove 125 in the base 118 which is configured to lock the O-ring 18 in position and thereby maintain the tension on the sheath 21. With the proper amount of tension placed upon the sheath 21, the effect is to maintain the primary seal between the peritoneal O-ring 16 and the interior abdominal wall 14, and the secondary seal between the base 118 and the exterior abdominal wall 14. The sealing cap 61 can then be attached to the proximal end of the base 118 and the patient can be insufflated with carbon dioxide to facilitate a laparoscopic procedure.

The sealing cap 61 can be removed at any time to allow transition from laparoscopic surgery to open surgery, if desired.

A further embodiment of the wound retractor 10 is illustrated in Figures 29-33 and includes three separate rings, the peritoneal ring 16, the external ring 18, and an intermediate ring 127, each attached to the sheath 21. The peritoneal O-ring 16 is designed to be placed inside the incision 12 while the eternal O-ring 18 remains external to the incision 12. The intermediate O-ring 127 may remain external to the incision 12 or may lie within the incision itself depending upon the final orientation of the rings 16, 18, 127, as discussed in greater detail below.

In this embodiment, the wound retractor has four different fixed lengths to accommodate abdominal walls of 4 different thicknesses. The first length, which is the longest, is achieved by simply placing the peritoneal O-ring 16 into the incision 12. The tension of the sheath 21 between the external O-ring 18 and the peritoneal O-ring 16 maintains the incision 12 in the open, retracted configuration. As illustrated in Figure 29, if the thickness of the abdominal wall 14 is less than the distance between the eternal O-ring 18 and the peritoneal O-ring 16, then a shorter length of the sleeve 21 can be selected.

The second length of the sleeve 21, which is less than the first length, is achieved by simply placing the peritoneal O-ring 16 into the incision 12, and then pulling the sheath upwards until the intermediate ring 127 is external to the incision 12. The tension on the sheath 21 between the intermediate O-ring 127 and the peritoneal O-ring

16 maintains the incision 12 in the open configuration as illustrated in Figure 30. If the thickness of the abdominal wall 14 is less than the distance between the intermediate O-ring 127 and the peritoneal O-ring 16, then a shorter length of the sleeve 21 can be selected.

The third length of the sleeve 21, which is less than the second length, is achieved by inserting the peritoneal O-ring 16 into the incision12 and then pulling the intermediate O-ring 127 outwardly and over the external O-ring 18. The tension of the sheath 21 between the peritoneal O-ring 16 and the combination of the external O-ring 18 and the intermediate O-ring 127 maintains the incision 12 in the open configuration. As illustrated in Figure 31, if the thickness of the abdominal wall 14 is less than the third length, then a shortened length of the sleeve 21 can be selected.

The fourth length of the sleeve 21, which is less than the third length, is achieved by first pulling the intermediate O-ring 127 through the external O-ring 18, and then pulling the intermediate O-ring 127 outwardly over the external O-ring 18. The tension of the sheath 21 between the peritoneal O-ring 16 and the combination of the external O-ring 18 and the intermediate O-ring 127 maintains the incision 12 in the open configuration. The 3-ring retractor of Figure 29 can therefore be positioned to effect four different lengths to accommodate variations in the thickness of the abdominal wall 14 from patient to patient.

A further advantage associated with this embodiment is that the device enables a surgeon to retract and protectively line an abdominal wall incision while being

able to easily adjust the device to accommodate variations from patient to patient in the thickness of the abdominal wall. The device is also very low in cost since it includes only four components, three O-rings and a tubular sheath.

Notwithstanding the foregoing description, it will be understood that many other modifications can be made to the various disclosed embodiments and method steps, without departing from the spirit and scope of the concept. For example, various sizes of the surgical device are contemplated as well as various types of constructions and materials. It will also be apparent that many modifications can be made to the configuration of parts as well as their interaction. For these reasons, the above description should not be construed as limiting the invention, but should be interpreted as merely exemplary of preferred embodiments. Those skilled in the art will envision other modifications within the scope and spirit of the present invention as defined by the following claims.

CLAIMS

1. A surgical retractor adapted for use in opening an incision in a body wall to facilitate access into a body cavity, comprising:

an interior anchor adapted for disposition interiorly of the body wall and having a size greater than that of the incision;

an exterior tensioning device adapted for disposition exteriorly of the body wall and having a size greater than the incision;

at least one tension element coupled to the interior anchor and adapted to pass through the incision to engage the exterior tension device; and

means carried with the exterior tensioning device for engaging the tension element at a predetermined location along the tension element to maintain a tensile force on the tension element as it passes through the incision.

2. The surgical retractor recited in Claim 1, wherein the tension element is a tubular sheath.

3. The surgical retractor recited in Claim 2, wherein the sheath is formed of an elastomeric material.

4. The surgical retractor recited in Claim 1, wherein the tension element comprises a ladder strap.

5. The surgical retractor recited in Claim 1, wherein the tension element comprises an elastomeric band.

6. The surgical retractor recited in Claim 1, wherein the tension element comprises a rope.

7. The surgical retractor recited in Claim 1, wherein the at least one tension element is included in a plurality of tension elements adapted to be spaced around the incision.

8. The surgical retractor recited in Claim 1, wherein the engaging means includes an engagement mechanism associated with the tension element for holding the tension element at the predetermined location in a releasably fixed relationship with the exterior tension device.

9. The surgical retractor recited in Claim 8, wherein the engagement mechanism comprises a hook.

10. The surgical retractor recited in Claim 1, wherein the engagement mechanism comprises a clamp.

11. A surgical retractor adapted for use in opening an incision in a body wall to facilitate access into a body cavity, comprising:

a tubular sheath having an axis extending between a proximal end and a distal end;

a distal ring disposed at the distal end of the sheath;

a proximal ring disposed at the proximal end of the sheath;

a middle ring axially moveable relative to the sheath at least a portion of the distance between the proximal ring and the distal ring;

the distal ring being adapted to retain the distal end of the sleeve interiorly of the body wall;

the proximal ring being adapted to retain the proximal end of the sheath exteriorly of the body wall with the sheath extending through the incision; and

the middle ring and the proximal ring having properties for cooperating to tension the sleeve between the middle ring and the distal ring to retract the incision.

12. The surgical retractor recited in Claim 11, wherein the sheath is formed of an elastomeric material.

13. The surgical retractor recited in Claim 12, wherein the proximal ring and the middle ring are sized and configured to facilitate stretching at least one of the proximal ring and the middle ring over the other of the proximal ring

and the middle ring to tension the sleeve between the middle ring and the distal ring.

14. The surgical retractor recited in Claim 11, wherein the distal ring has properties for moving between a low profile state to facilitate insertion through the incision in the body wall, and a high profile state to facilitate retention of the distal end of the sheath interiorly of the body wall.

15. The surgical retractor recited in Claim 14, wherein the distal ring is formed of an elastomeric material.

16. The surgical retractor adapted for use in opening an incision in a body wall to facilitate access into a body cavity; comprising:

a tubular sheath having an axis extending between a proximal end and a distal end;

a distal ring disposed at the distal end of the sheath;

at least one proximal ring disposed along the sheath at a predetermined location relative to the distal ring;

means for engaging the at least one proximal ring at the predetermined location and around the incision to tension the sheath through the incision and between the distal ring and the at least one proximal ring.

17. The surgical retractor recited in Claim 16, wherein the proximal ring is fixed to the sheath at the predetermined location.

18. The surgical retractor recited in Claim 17, wherein the proximal ring is one of a series of proximal rings each fixed to the sleeve at a different axial distance from the distal ring.

19. The surgical retractor recited in Claim 17, wherein the engaging means comprises a circular clip for engaging the proximal ring and fixing the proximal ring at the predetermined location.

20. The surgical retractor recited in Claim 18, wherein:

the series of proximal rings comprises a series of loops; and

the circular means comprises an insert mountable in one of the loops at the associated predetermined location.

21. The surgical retractor recited in Claim 19, wherein:

each of the proximal rings in the series has a cross sectional configuration; and

the circular clip has portions defining a slot with the cross-sectional configuration.

22. The surgical retractor recited in Claim 16, wherein the proximal ring is movable relative to the sheath to the predetermined location; and

the means engages the sheath and the proximal ring at the predetermined location to fix the proximal ring to the sleeve at the predetermined location.

23. The surgical retractor recited in Claim 22, wherein the proximal ring and the engagement means form a cooperating structure which sandwiches the sheath between the proximal ring and the circular means at the predetermined location.

24. The surgical retractor recited in Claim 23, wherein the proximal ring is disposed outwardly of the sheath and the circular means is disposed inwardly of the sheath.

25. The method for retracting an incision extending through a body wall of the patient, comprising the steps of:

providing a tubular sheath having an axis extending between a proximal end and a distal end;

introducing the distal end of the tubular sheath through the incision to the distal side of the body wall;

leaving the proximal end of the sleeve on the proximal side of the body wall;

anchoring the distal end of the sleeve on the distal side of the body wall;

tensioning the sleeve axially to retract the incision; and

fixing the proximal end of the sleeve on the proximal side of the body wall to maintain the tension on the sleeve and the retraction of the incision.

26. The method recited in Claim 25, wherein the tensioning step includes the steps of:

providing a tensioning ring fixed to the sheath at a predetermined location;

engaging the tensioning ring at the predetermined location; and

drawing the tensioning ring proximally of the body wall to tension the sleeve.

27. The method recited in Claim 26, wherein:

the providing step includes the step of providing the tensioning ring with first screw threads, and providing an engaging ring with second screw threads complimentary to the first screw threads of the tensioning ring; and

the drawing step includes the step of screwing the engaging ring relative to the tensioning ring.

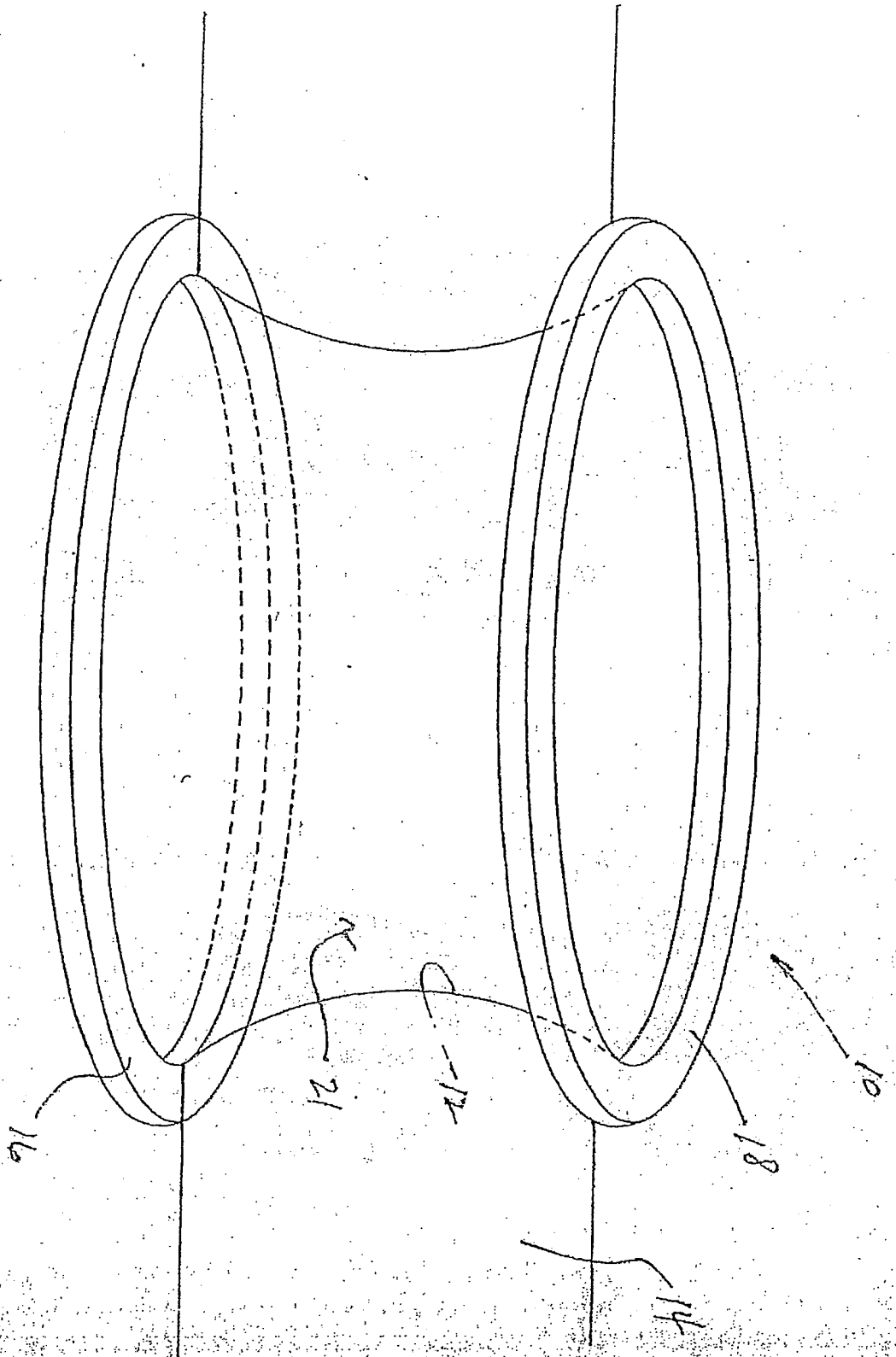


Fig. 1

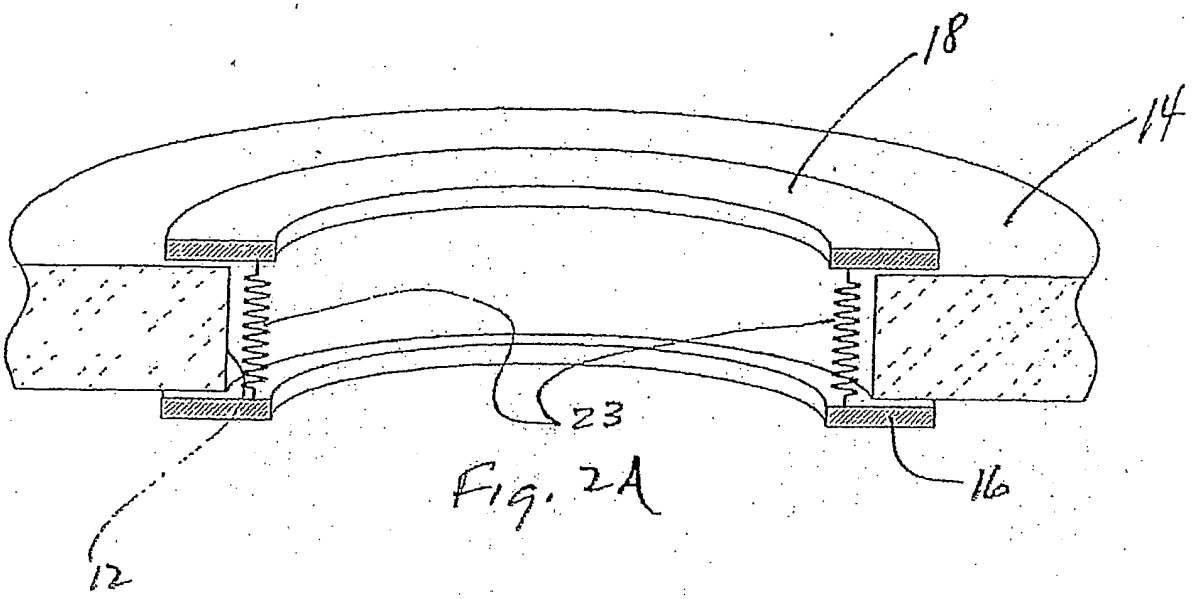


Fig. 2A

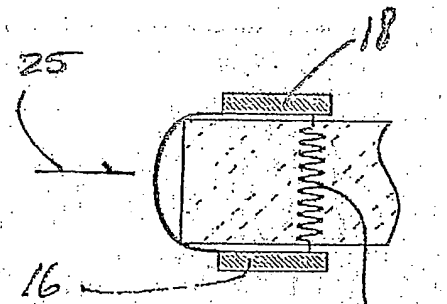


Fig. 2B

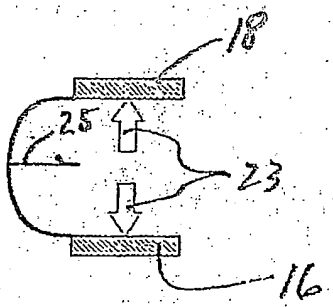


Fig. 2C

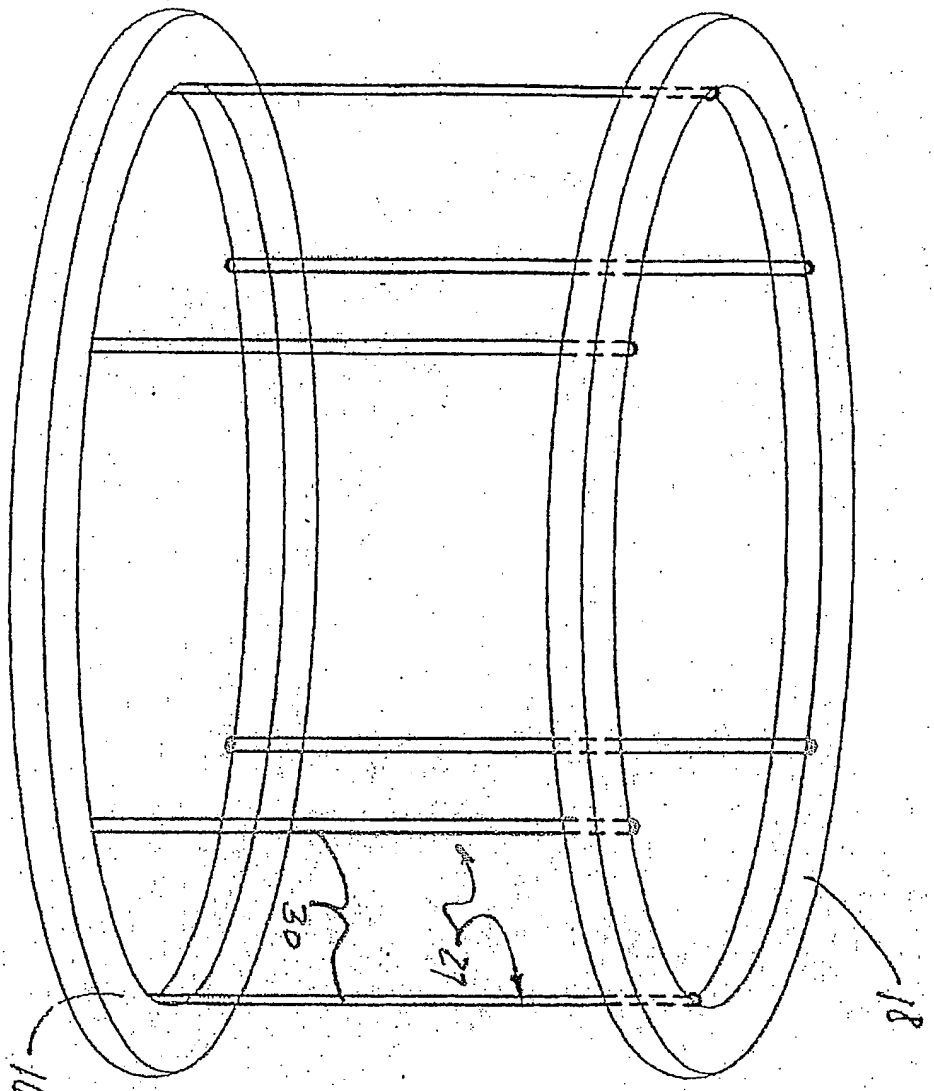


Fig. 3

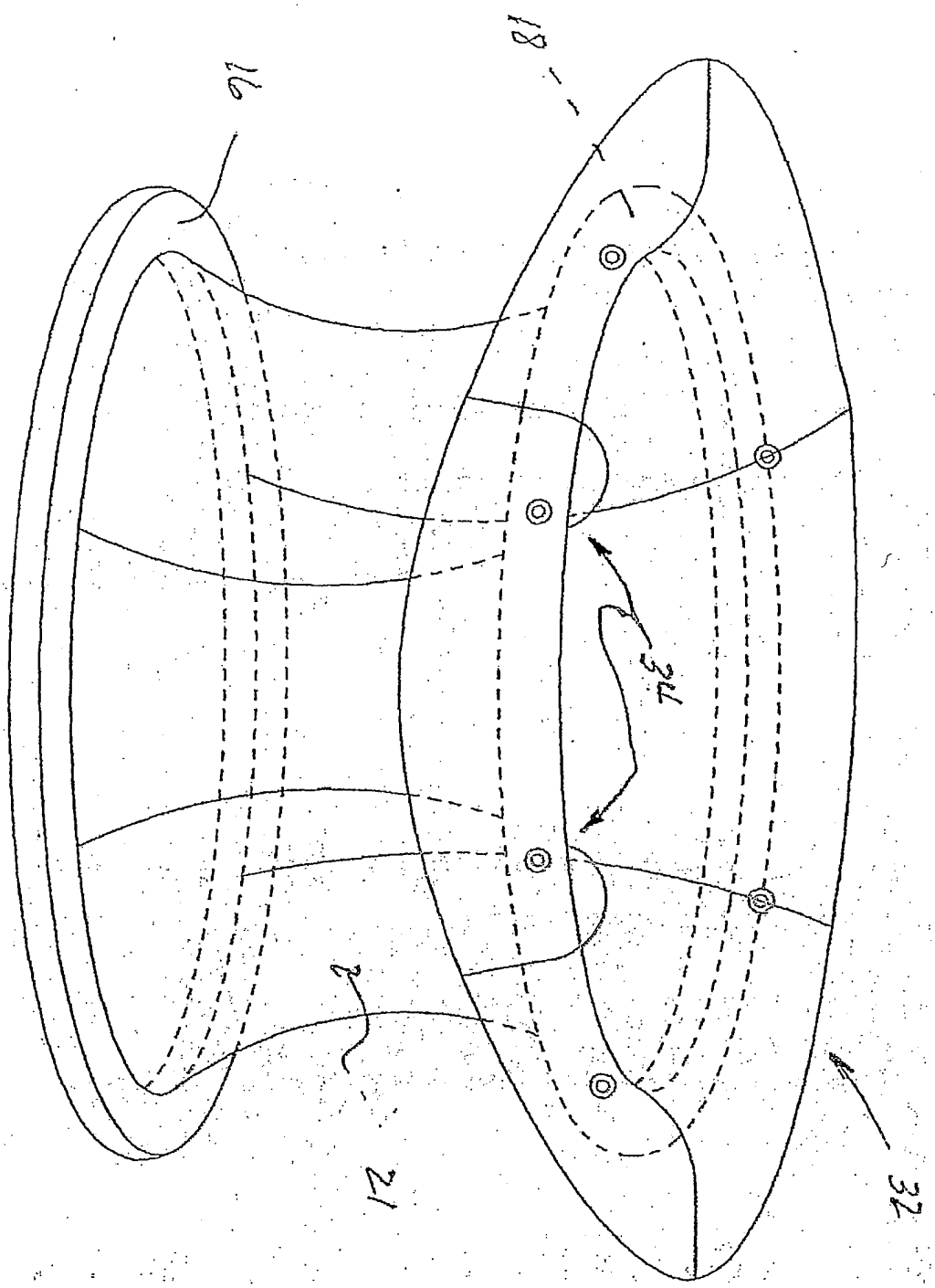


Fig. 4

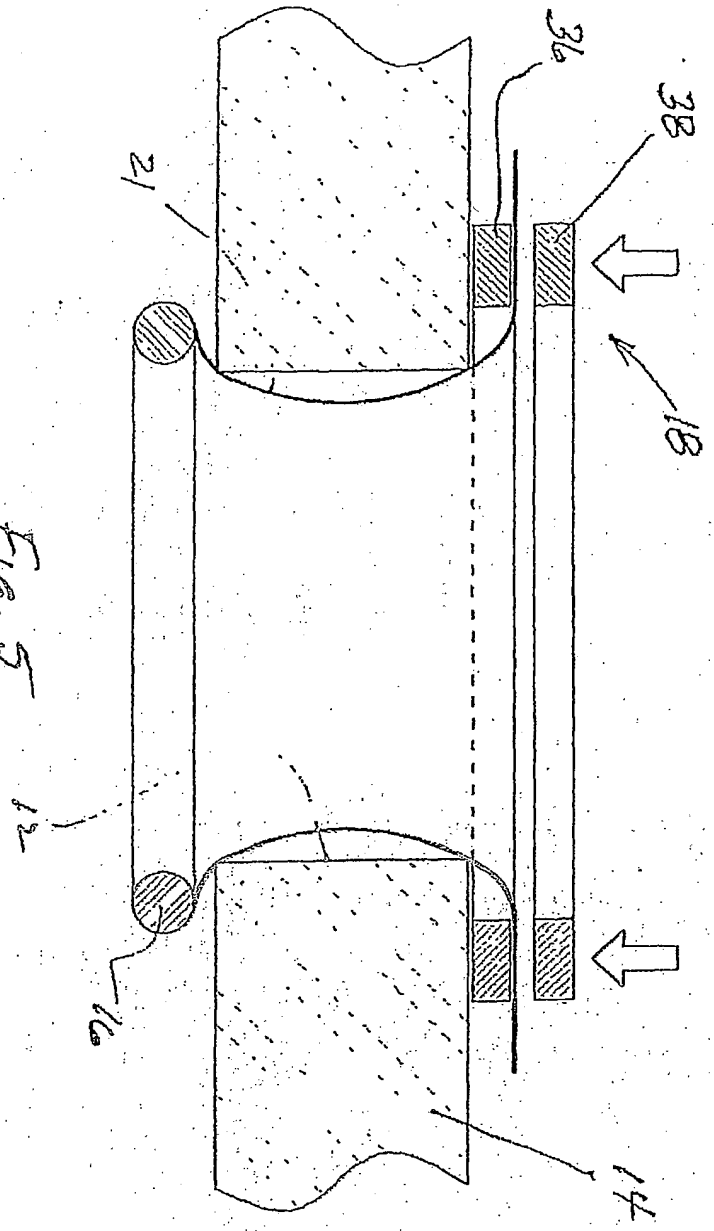


Fig. 5

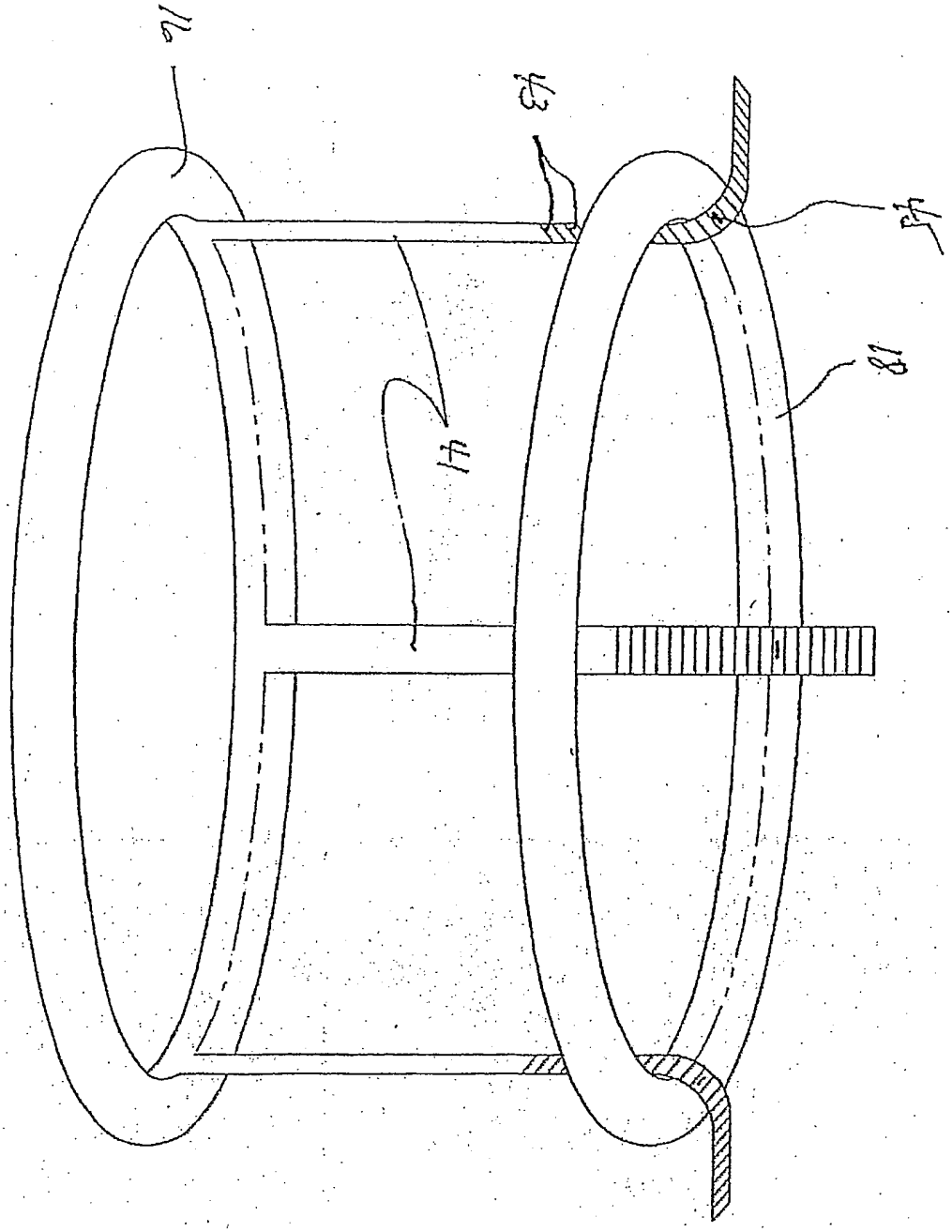


Fig. 6

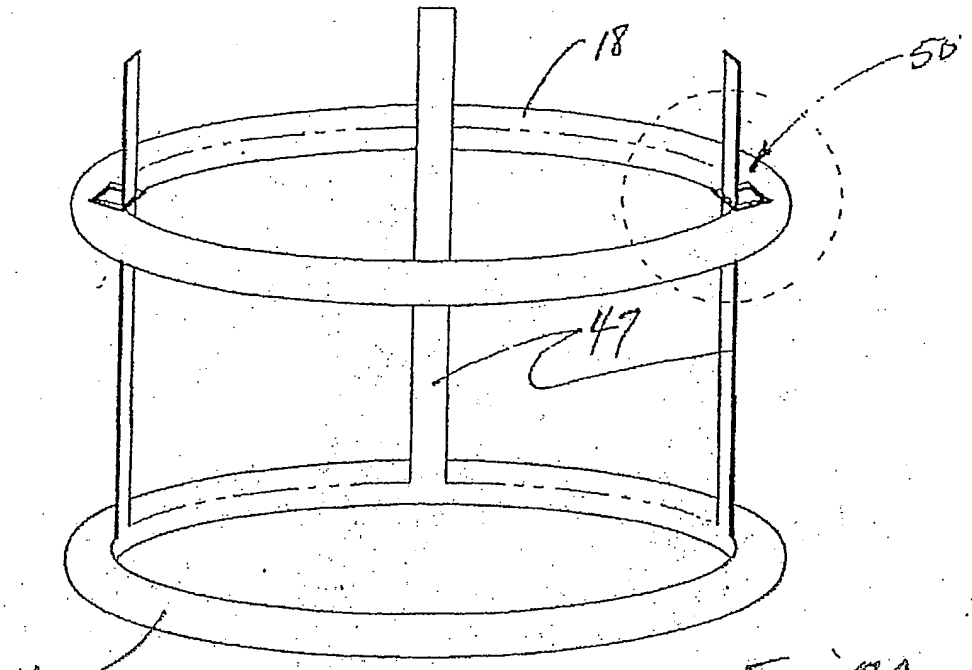


Fig. 7A

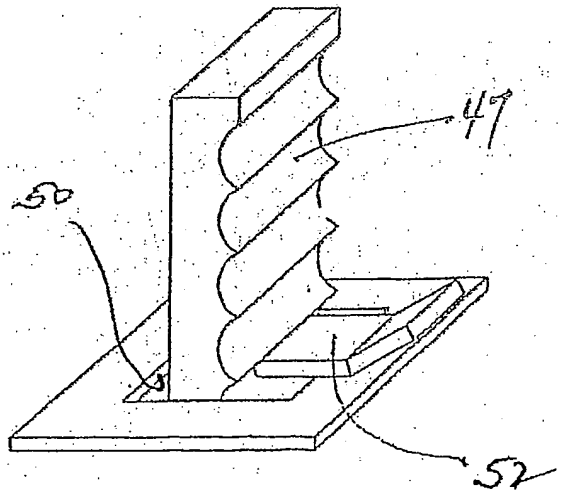


Fig. 7B

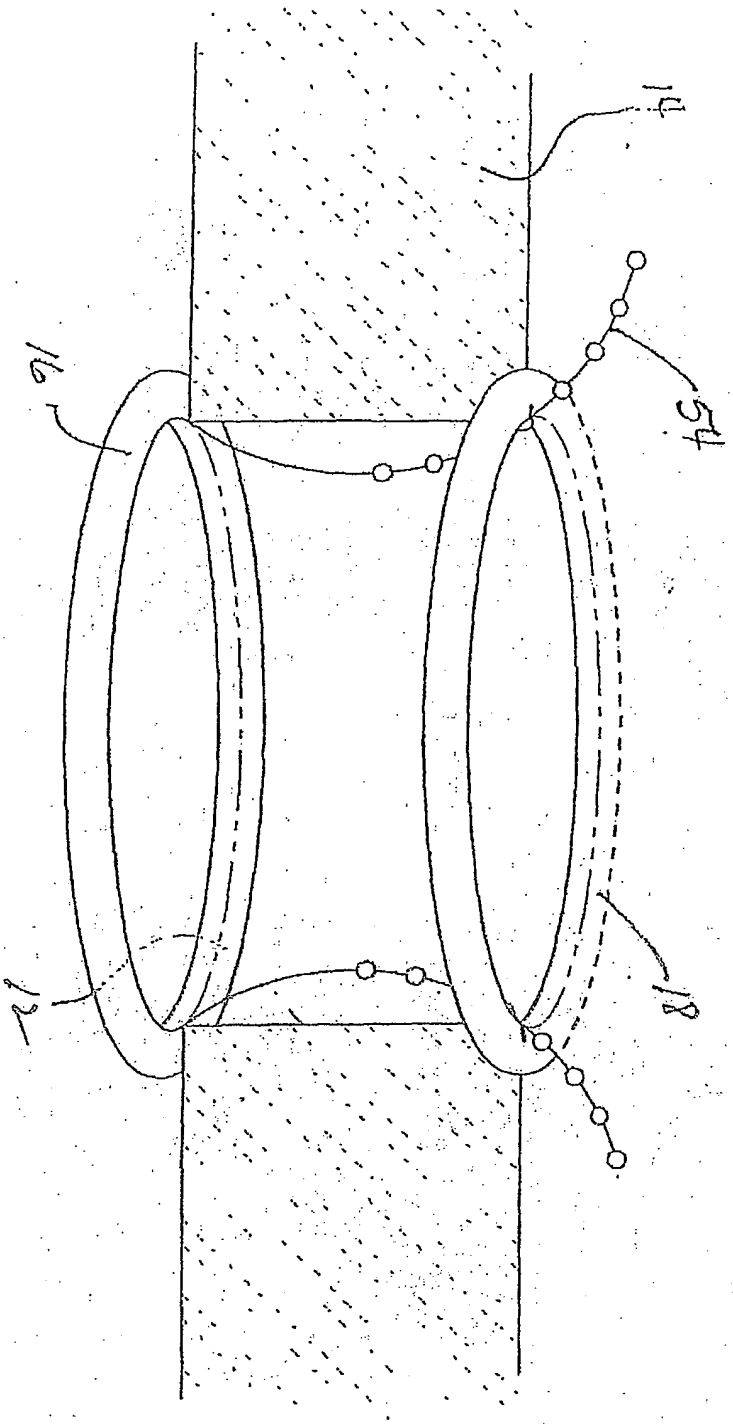


Fig. 8

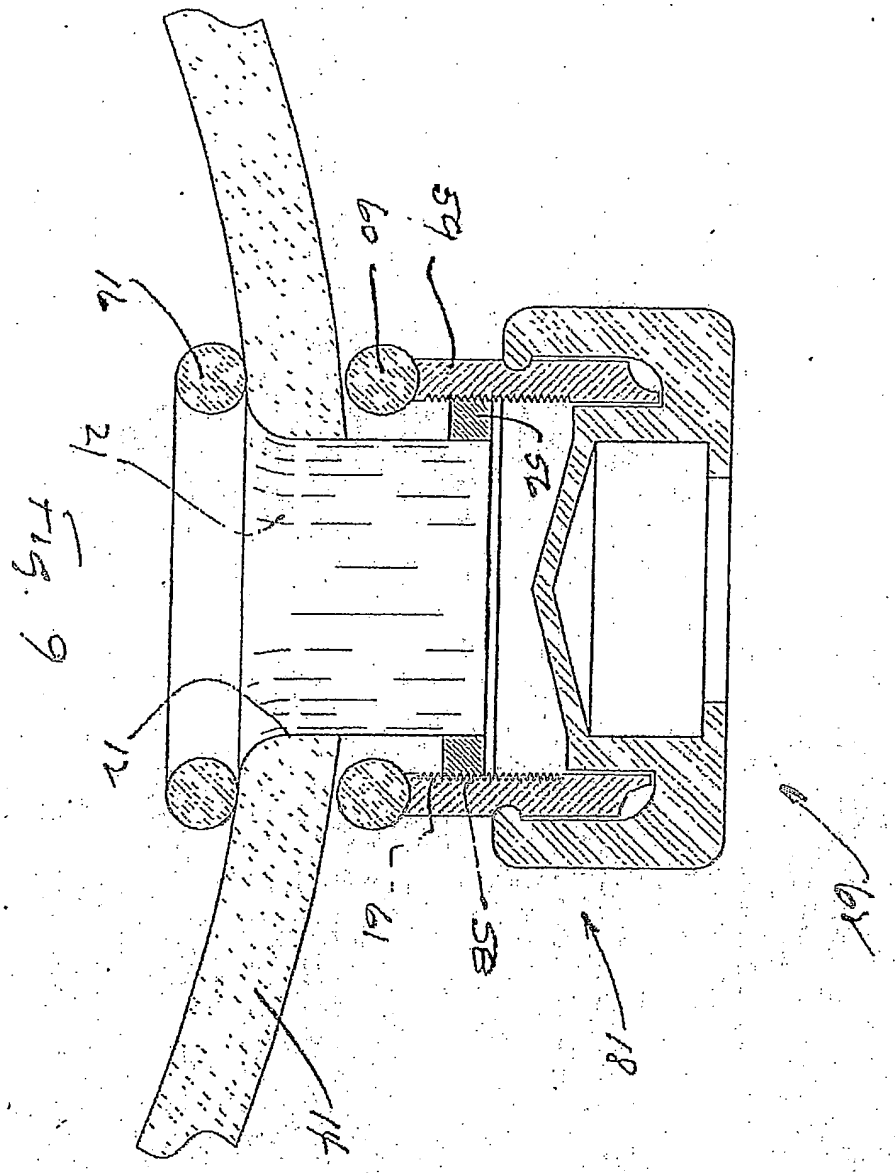


Fig. 9

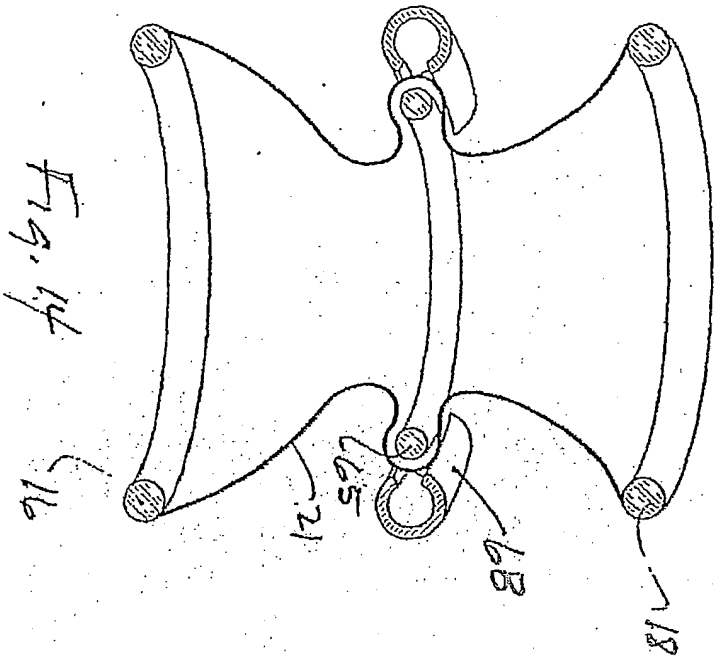


Fig. 14

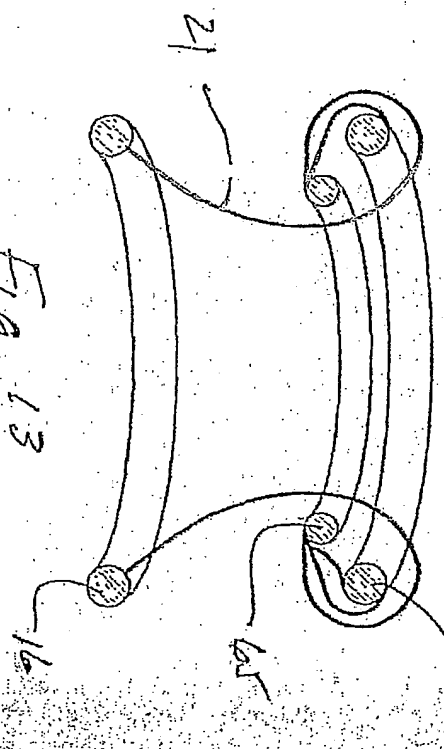


Fig. 13

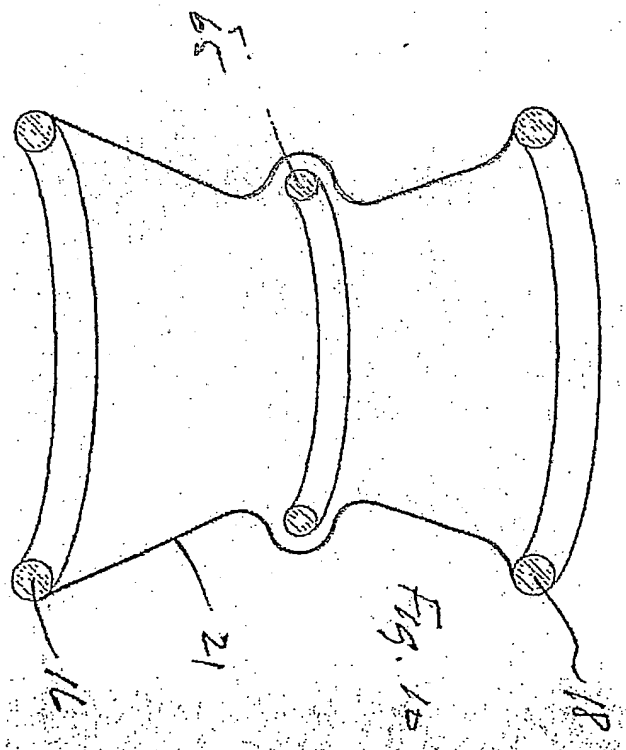


Fig. 15

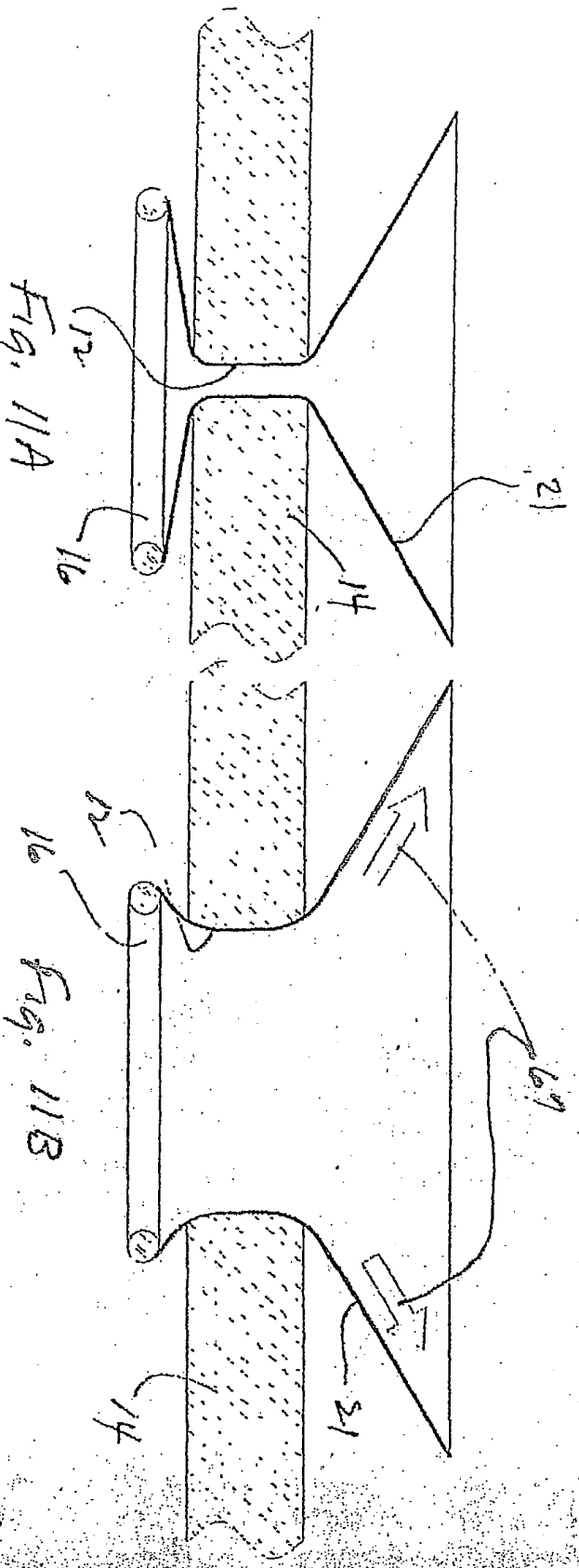


Fig. 11A

Fig. 11B

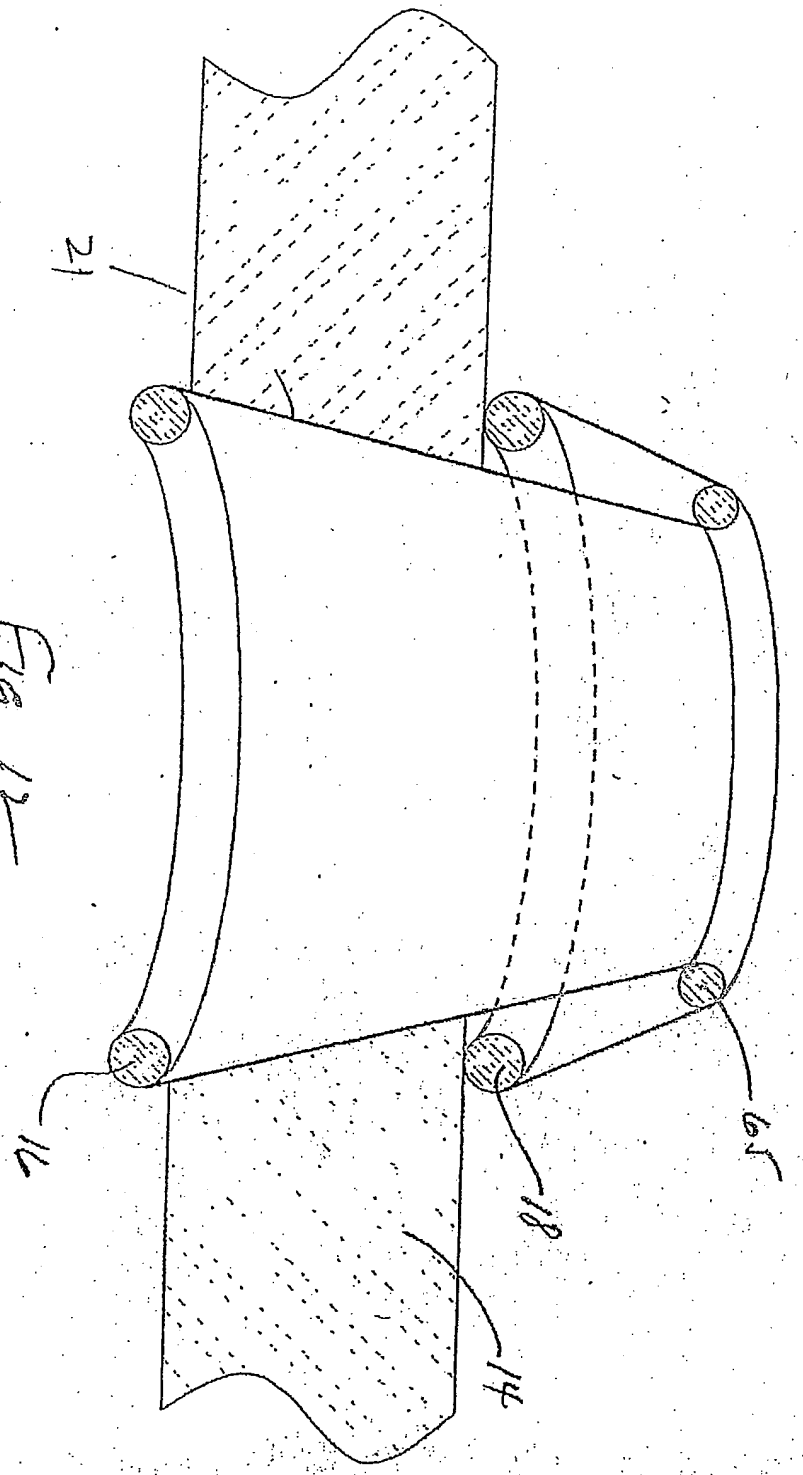


Fig. 12

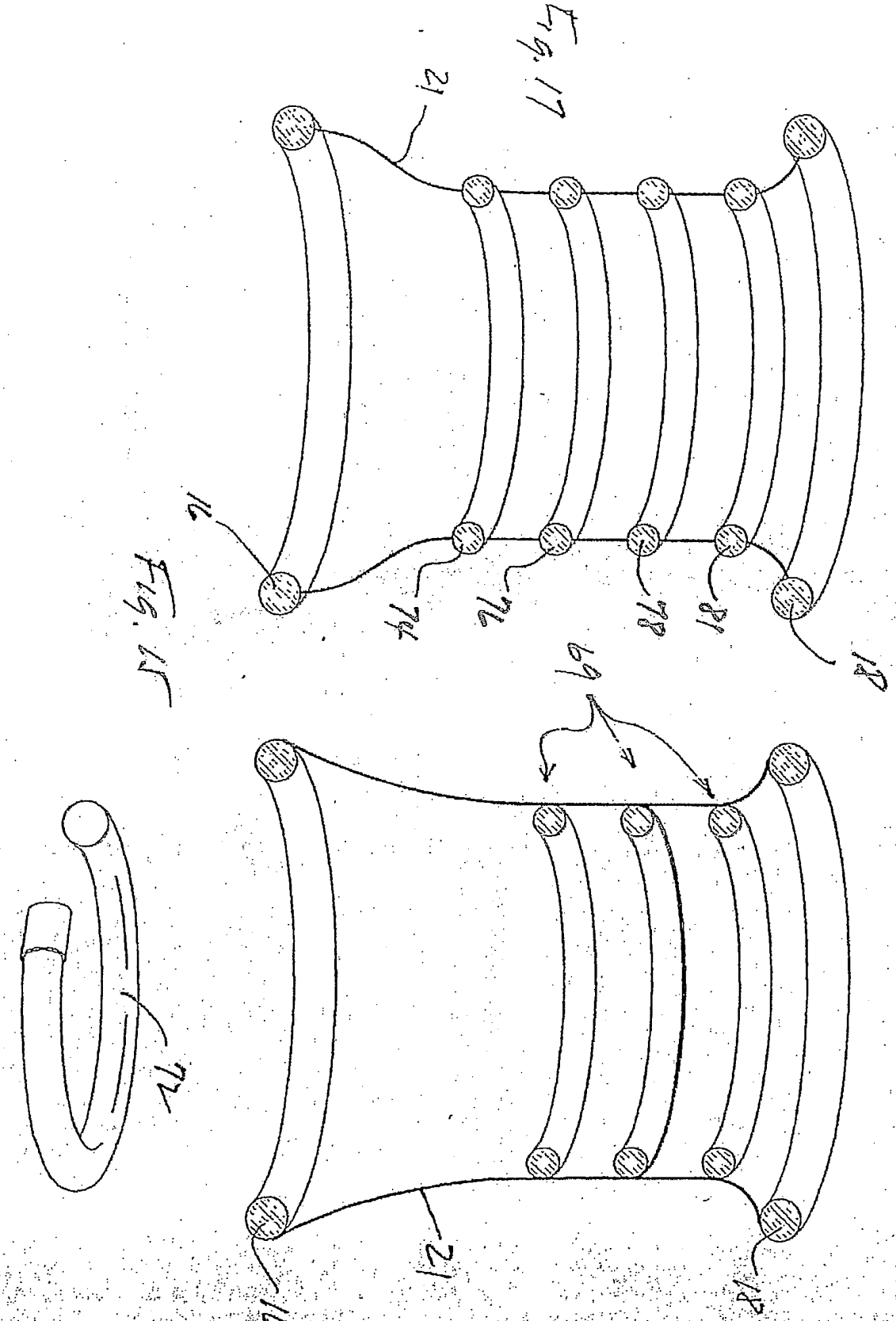


Fig. 17
12
21
Fig. 17
74
74
78
18
81
69
72
11
12
81

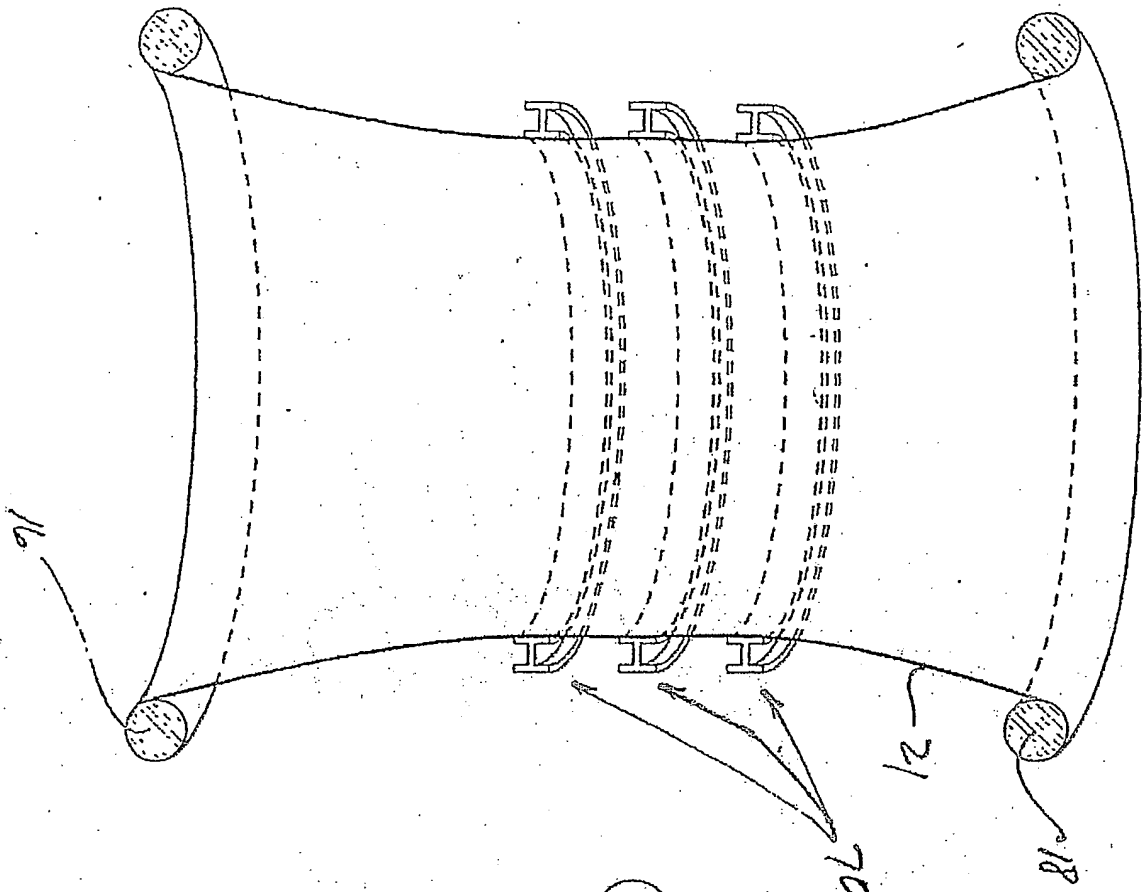
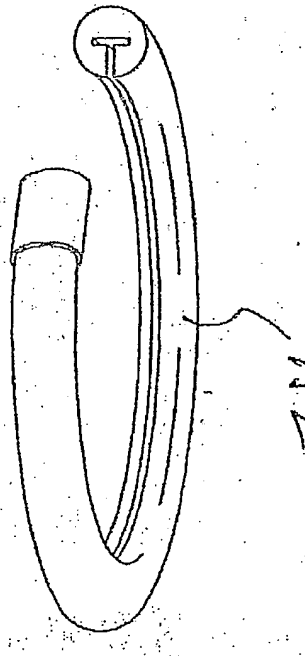


Fig. 15



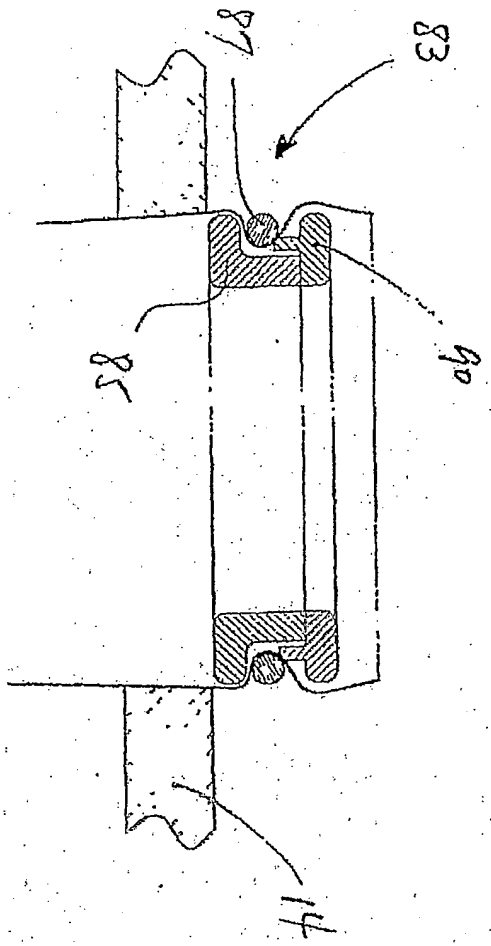


Fig. 15

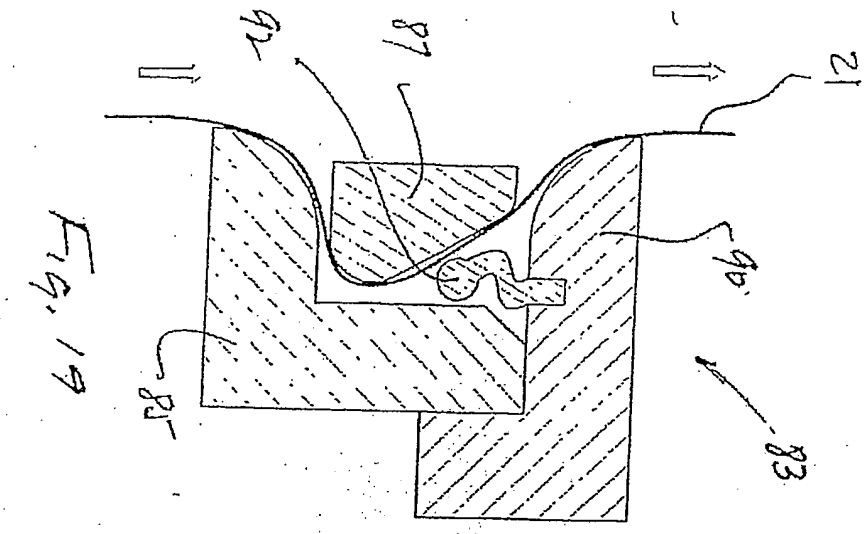


Fig. 19

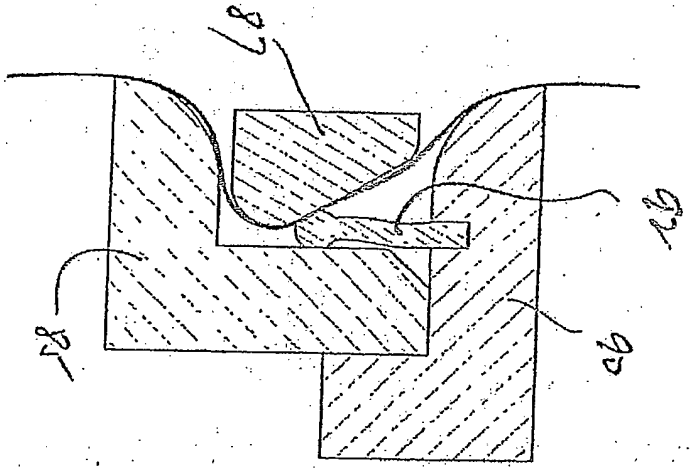


Fig. 20

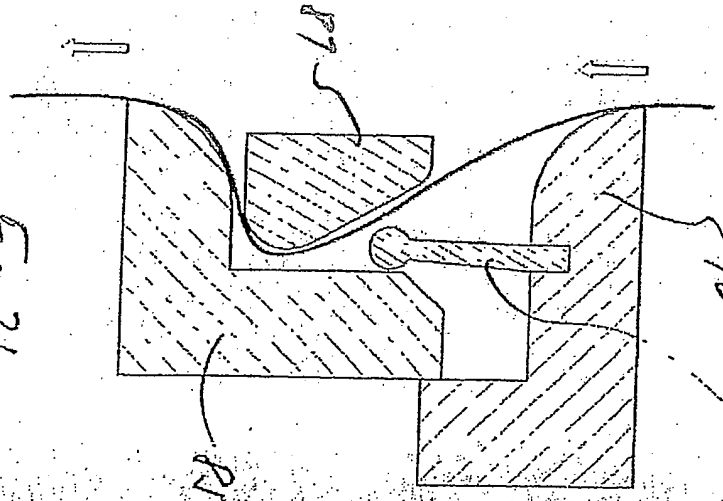


Fig. 21

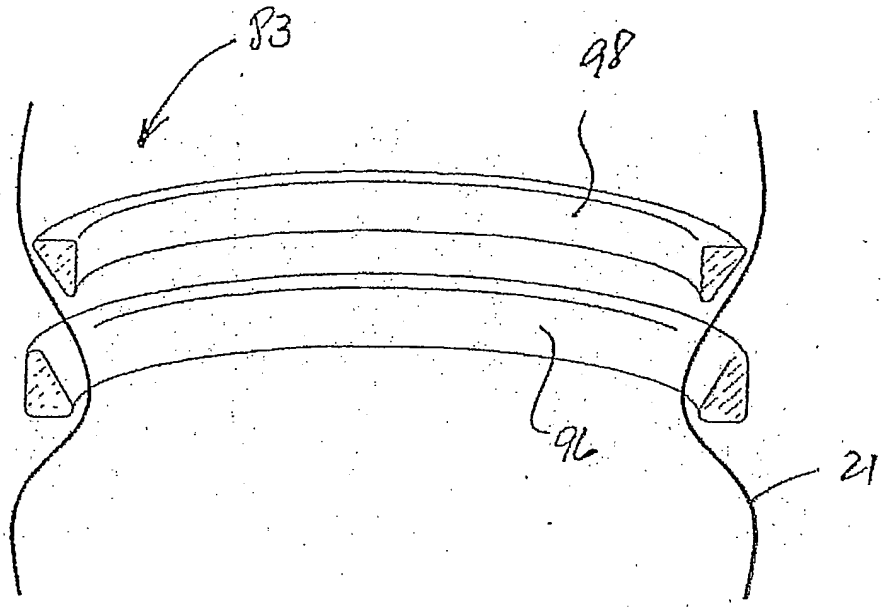


Fig. 23

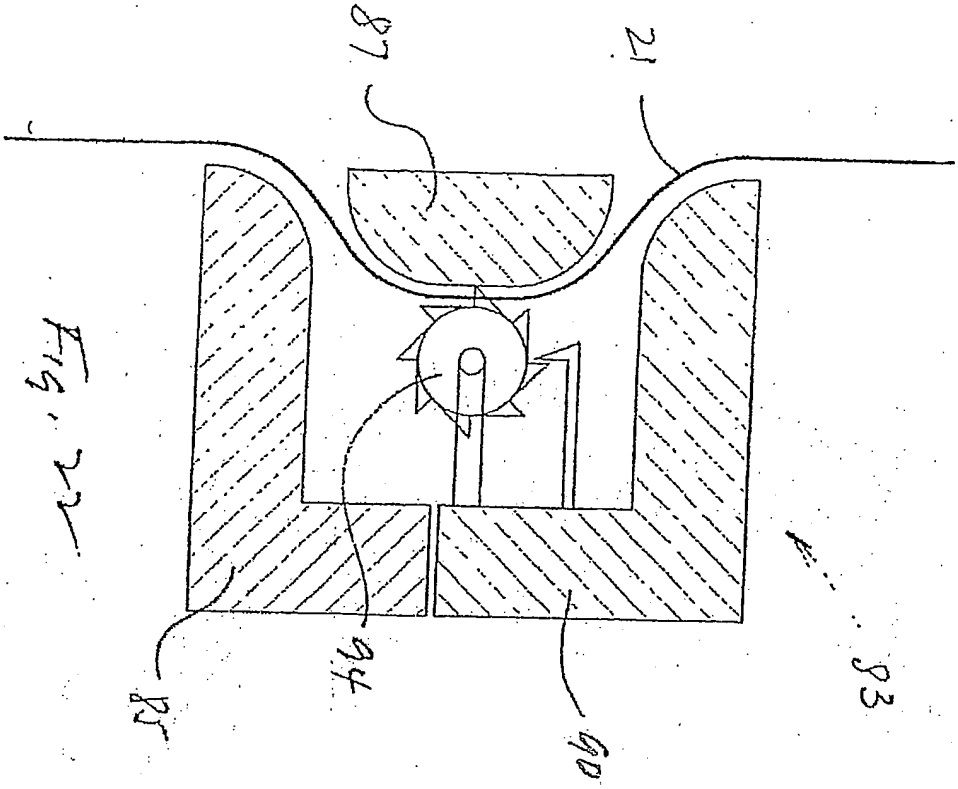


Fig. 23

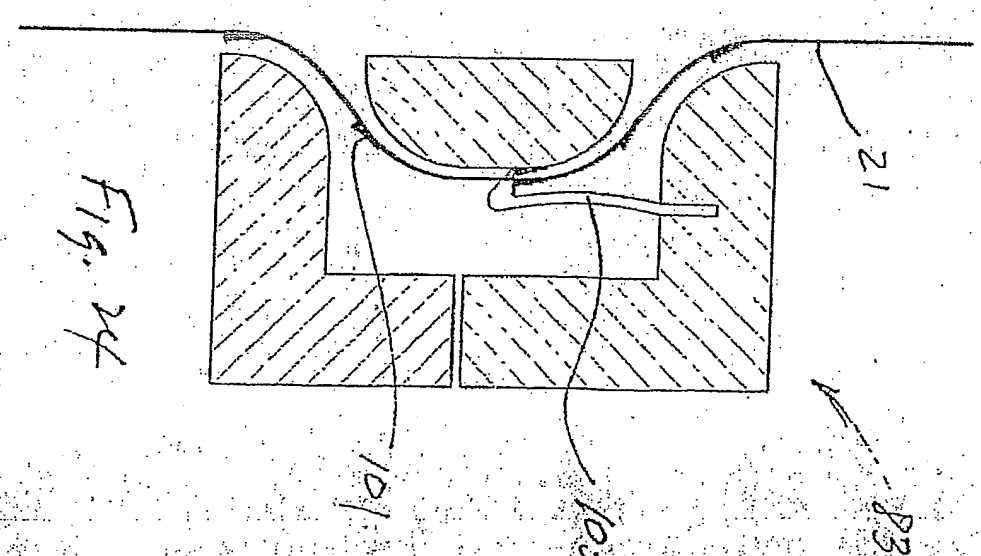


Fig. 24

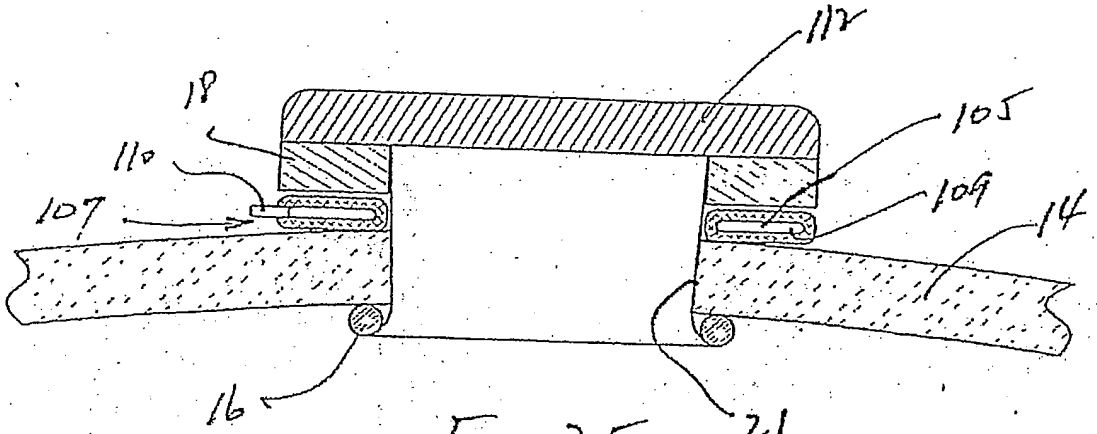


Fig. 25

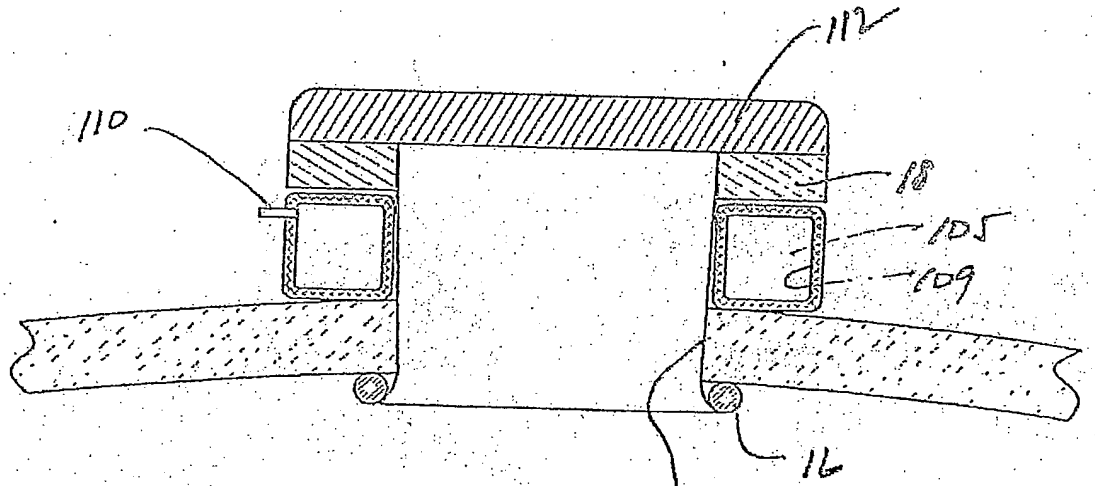


Fig. 26

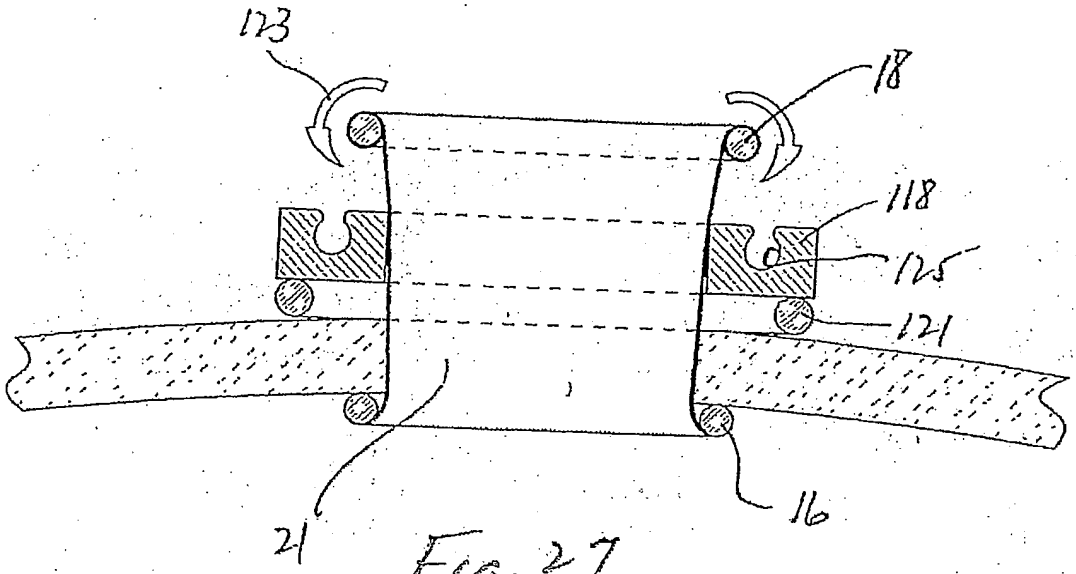


Fig. 27

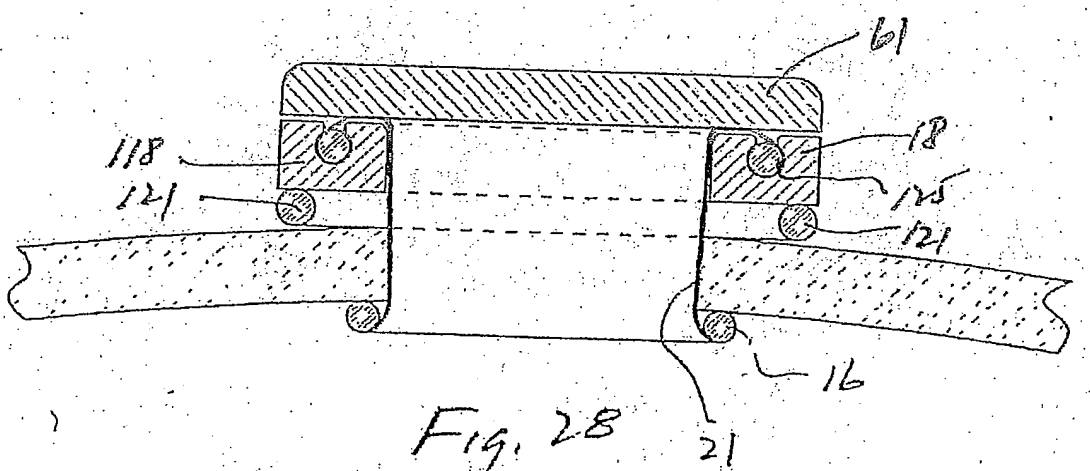


Fig. 28

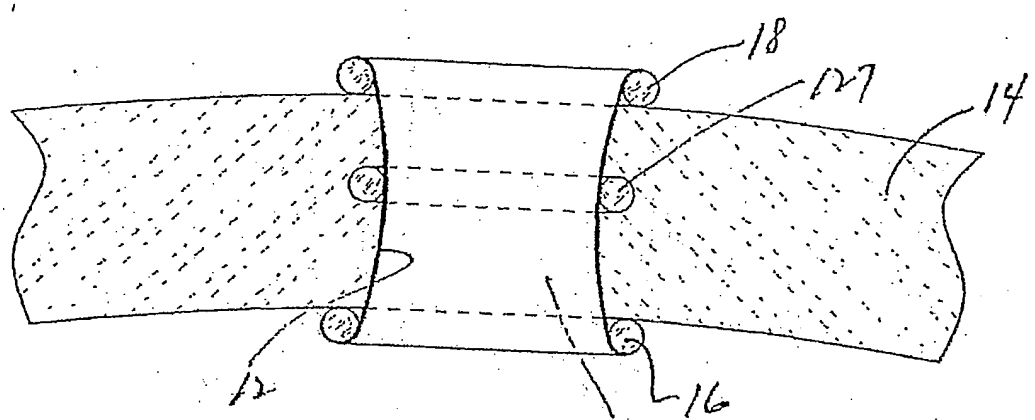


Fig. 29

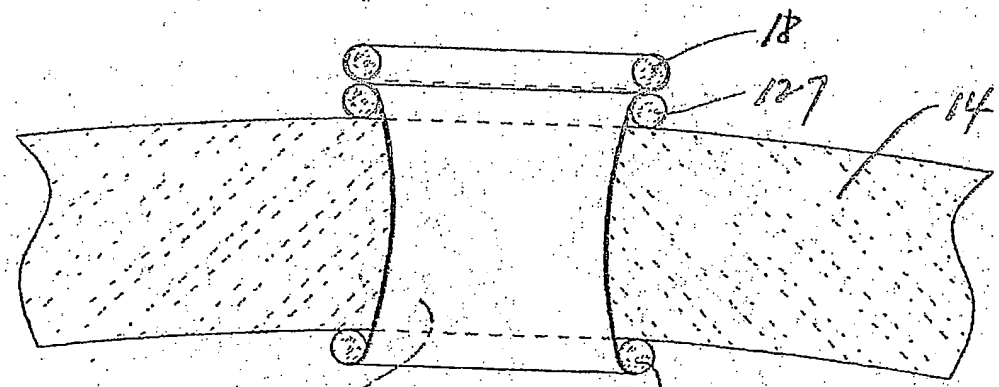


Fig. 30

Fig. 32

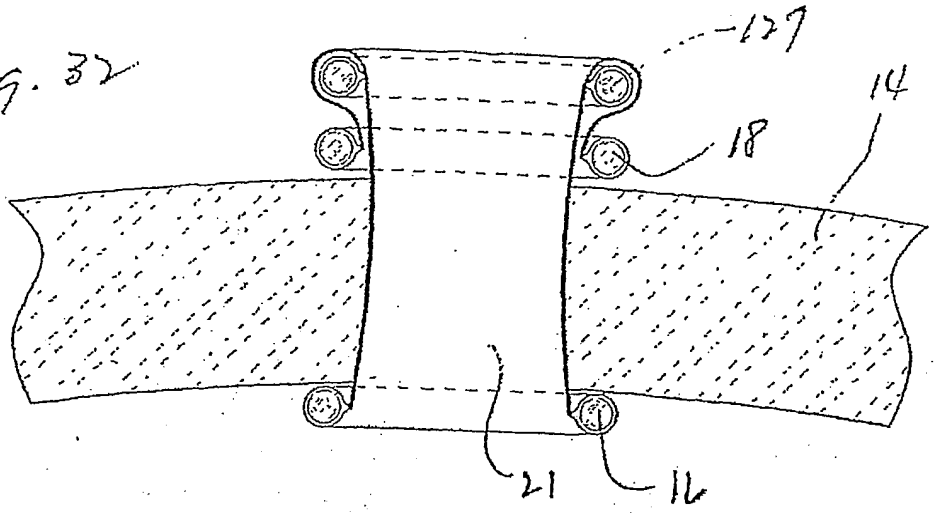


Fig. 31

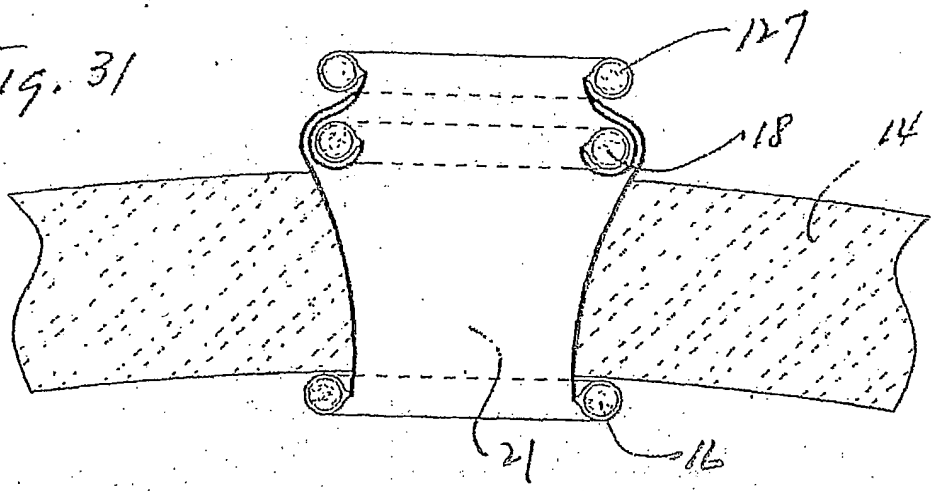
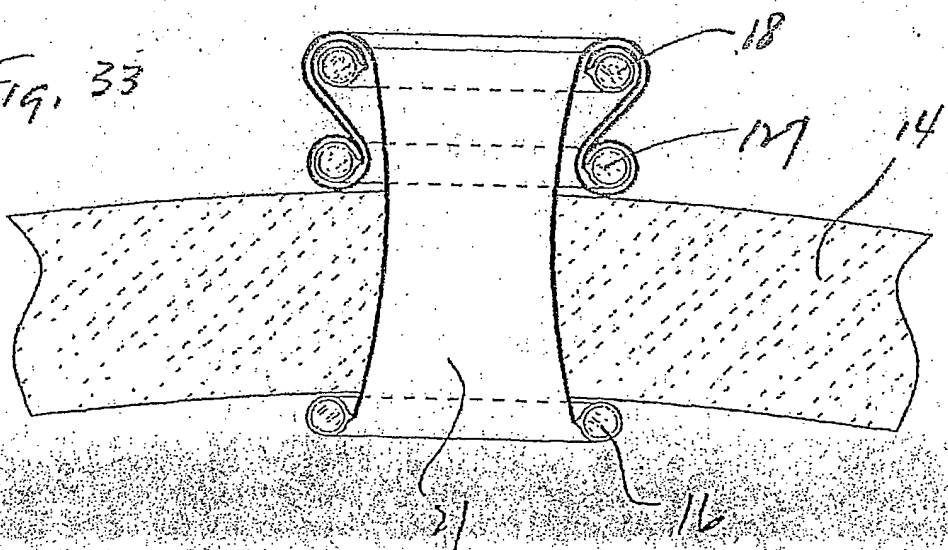


Fig. 33



(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
10 September 2004 (10.09.2004)

PCT

(10) International Publication Number
WO 2004/075741 A3

(51) International Patent Classification[7]: A61B 1/32

(21) International Application Number: PCT/US2004/005487

(22) International Filing Date: 25 February 2004 (25.02.2004)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/449,857 25 February 2003 (25.02.2003) US

(71) Applicant *(for all designated States except US)*: APPLIED MEDICAL RESOURCES CORPORATION [US/US]; 22872 Avenida Empresa, Rancho Santa Margarita, CA 92688 (US).

(71) Applicant and
(72) Inventor *(for all designated States except US)*: PINGLETON, Edward, D. [US/US]; 26993 Albillo Court, Laguna Niguel, CA 92677 (US).

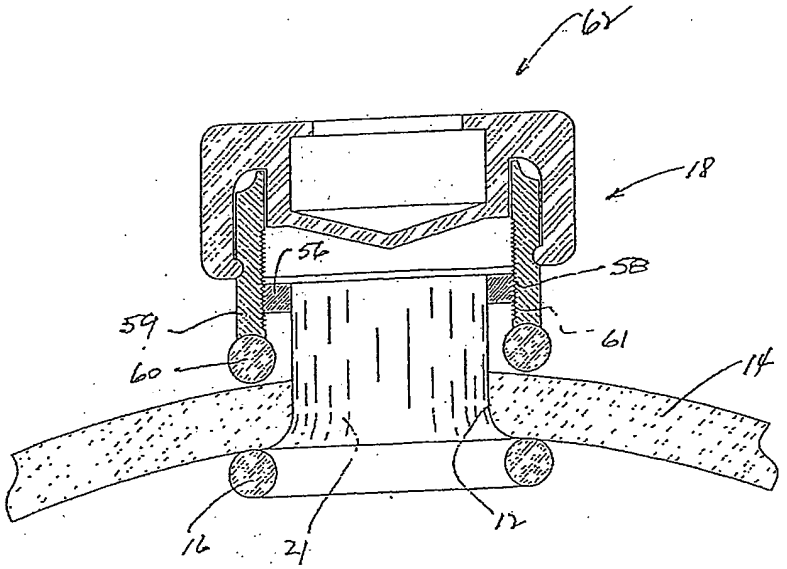
(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: BRUSTAD, John [US/US]; 34056 Formosa Drive, Dana Point, CA 92629 (US). EWERS, Richard [US/US]; 1437 W. Malvern, Fullerton, CA 92833 (US). HILAL, Nabil [US/US]; 25291 Spindlewood, Laguna Niguel, CA 92677 (US). ADLPARVAR, Payam [US/US]; 21861 Michigan Lane, Lake Forest, CA 92630 (US). TAYLOR, Scott, V. [US/US]; 27851 Encanto, Mission Viejo, CA 92692 (US). DULAK, Gary, R. [US/US]; 6 Mojo Court, Newport Beach, CA 92663 (US). DUNN, Michael, J. [US/US]; 2408 N. Louise, Santa Ana, CA 92706 (US). MORALES, Norman, L. [US/US]; 38700 Tyson Lane, #307, Fremont, CA 94536 (US). HART, Charles, C. [US/US]; 126 Marvin Gardens, Summerville, SC (US). BOWES, Robert, R., II [US/US]; 28520 Wood Canyon, #81#2212, Aliso Viejo, CA 92656 (US).

(74) Agent: MYERS, Richard; 22872 Avenida Empresa, Rancho Santa Margarita, CA 92688 (US).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE,

[Continued on next page]

(54) Title: WOUND RETRACTOR FOR USE IN HAND ASSISTED LAPAROSCOPIC SURGERY



(57) Abstract: A surgical retractor (10) is adapted for use in opening an incision (12) in a body wall (14) to facilitate access into a body cavity. The retractor includes an interior anchor (16) that is disposed interiorly of the body wall and an exterior tensioning device (56) that is disposed exteriorly of the body wall. At least one tension element (21) is coupled to the interior anchor and adapted to pass through the incision to engage the exterior tensioning device. Engaging elements (59, 62) are provided on the exterior tensioning device to engage the tension element and to maintain a tensile force on the tension element as it passes through the incision. Multiple concentric rings can also be used to maintain a tensile force on the tension element.

WO 2004/075741 A3

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US04/05487

A. CLASSIFICATION OF SUBJECT MATTER
IPC(7) : A61B 1/32
US CL : 600/206
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
U.S. : 600/206, 184, 201, 204, 227, 228, 235; 128/845, 846, 849, 850, 855, 856, 888

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6,254,533 B1 (FADEM et al.) 03 July 2001 (03.07.2001), See figures 1, 3A, 3B, column 4, lines 39-67 and column 5, lines 1-18)	1, 2, 3, 5, 8, 16,17,19,21,22,23,25, 26
X	US 6,450,983 B1 (RAMBO) 17 September 2002 (17.09.2002), See figures 1, 6 and 7, column 6, lines 3-67, column 7, lines 1-67 and column 8, lines 1-67.	1,2,3,5,8,10,16,17,22, 25,26
X	US 2001/0037053 A1 (BONADIO et al.) 01 November 2001 (01.11.2001), See figures 14, 17, 18, 20 and 22, Paras [0094] and [0095].	1,4,5,6,7,8,10
X	US 6,254,534 B1 (BUTLER et al.) 03 July 2001 (03.07.2001), See figures 1-3, 5, 8(a) and 8(b) and column 4, lines 12-56.	1,2,3,5,6,8-14,15,16,17,19,22-26

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
20 July 2004 (20.07.2004)	20 AUG 2004
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703)305-3230	Authorized officer Kevin Shaver Telephone No. (703) 308-0858

Form PCT/ISA/210 (second sheet) (July 1998)

This Page is Inserted by IFW Indexing and Scanning Operations and is not part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☐ BLACK BORDERS
- ☐ IMAGE CUT OFF AT TOP, BOTTOM OR SIDES
- ☐ FADED TEXT OR DRAWING
- ☐ BLURRED OR ILLEGIBLE TEXT OR DRAWING
- ☐ SKEWED/SLANTED IMAGES
- ☐ COLOR OR BLACK AND WHITE PHOTOGRAPHS
- ☑ GRAY SCALE DOCUMENTS
- ☐ LINES OR MARKS ON ORIGINAL DOCUMENT
- ☐ REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY
- ☐ OTHER: _____

IMAGES ARE BEST AVAILABLE COPY.
As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.